# Commission on Risk Assessment and Risk Management

## *Risk Assessment and Risk Management in Regulatory Decision-Making*

DRAFT REPORT
FOR
PUBLIC REVIEW AND COMMENT

## Appendices

June 13, 1996

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# Appendix A.1

# Biographies of Commission Members

**COMMISSION ON RISK ASSESSMENT AND RISK MANAGEMENT**

**Member Biographies**

**Dr. Gilbert S. Omenn**, Chair.

Dr. Omenn is Professor of Environmental Health and of Medicine and Dean of the School of Public Health and Community Medicine at the University of Washington, Seattle. His research and public policy interests include genetic predisposition to environmental and occupational health hazards, chemoprevention of cancers, health promotion for older adults, and risk analysis. From 1977 to 1981, Dr. Omenn was a Deputy Science and Technology Adviser in the White House Office of Science and Technology Policy and then an Associate Director of the Office of Management and Budget. As the first Science and Public Policy Fellow at The Brookings Institution in Washington, DC., he coauthored the influential 1981 study, Clearing the Air: Reforming the Clean Air Act. The author of 380 research papers and scientific reviews, as well as author/editor of 14 books, Dr. Omenn received his A.B. from Princeton University, his M.D. from Harvard, and a Ph.D. in genetics from the University of Washington.

**Alan C. Kessler**, Vice-Chair.

A partner in the Philadelphia office of the law firm of Buchanan Ingersoll Professional Corporation, Mr. Kessler has extensive experience in the defense and litigation of major class action toxic tort suits in federal and state courts, as well as experience in the successful defense and prosecution of major federal antitrust and securities class action suits. Three times elected as a Township Commissioner for the Lower Merion Township in Montgomery County, Pennsylvania (population 58,000), Mr. Kessler also has been appointed by three successive Philadelphia mayors to various city boards and commissions. He also has been an advisor to a number of mayoral, gubernatorial, senatorial and presidential campaigns, and served on President Clinton's transition team. Mr. Kessler received his B.A. from the University of Delaware and his law degree from the University of Maryland. He was appointed to the Commission by President Clinton.

**Norman T. Anderson**

Mr. Anderson is Director of Research for the American Lung Association of Maine. President of the Maine Biological and Medical Sciences Symposium, he also is a member of the American Association for the Advancement of Science. He was a regional air toxicologist for the U.S. Environmental Protection Agency in Boston; a regulatory toxicologist for the Maine Bureau of Health, and an environmental health scientist for the Maine Department of Environmental Protection. He also has served on numerous environmental health advisory committees at the state and local level. Mr. Anderson received his B.A. from Brown University and his Masters of Science in Public Health from the University of North Carolina in Chapel Hill. He also has studied immunology and pathology at the Boston University School of Medicine.

**Dr. Peter Y. Chiu**

Dr. Chiu is Senior Physician and Service Committee Chair for The Kaiser Permanente Medical Group in Milpitas, CA, and an Assistant Clinical Professor at the Stanford University Medical School. Dr. Chiu has been a Fellow of the American Academy of Family Physicians since 1989, and also has been a registered civil engineer in California since 1972. He served as the principal environmental engineer for the Association of Bay Area Governments between 1976 and 1979 and was responsible for planning, organizing and directing environmental management programs for the San Francisco Bay area. He also served on the California Regional Water Quality Control Board from 1979 to 1984. Dr. Chiu received his B.S. in Civil Engineering, his Masters of Public Health degree, and his Doctor of Public Health degree from the University of California, Berkeley; and his M.D. degree from Stanford University.

**Dr. John Doull**

Dr. Doull is a Professor of Pharmacology and Toxicology and Therapeutics at the University of Kansas Medical Center. A former president of the American Board of Toxicology and the Society of Toxicology, Dr. Doull served on the boards of the American Academy of Clinical Toxicology and The Toxicology Forum. Dr. Doull has also served as a consultant to numerous government agencies, private institutes, foundations and businesses. He is the recipient of many professional honors, including one named for him, the John Doull Award presented by the Mid-America Chapter of the Society of Toxicology. Dr. Doull received his B.S. in Chemistry from Montana State College, and his Ph.D. in Pharmacology and M.D. degrees from the University of Chicago.

**Dr. Bernard Goldstein**

Dr. Goldstein is Director of the Environmental and Occupational Health Sciences Institute, a joint program of the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School and Rutgers University, and Chairman of the Department of Environmental and Community Medicine. He is a former member of the New York University faculty and a former president of the Association of University Environmental Health Sciences Centers. Dr. Goldstein has undertaken many major consultation and committee assignments. He has published more than 200 articles and book chapters related to environmental sciences and public policy. Dr. Goldstein received his B.S. degree from the University of Wisconsin and his M.D. from New York University School of Medicine.

**Dr. Joshua Lederberg**

Dr. Lederberg, a Noble Prize winning research geneticist, is President Emeritus of The Rockefeller University and remains a professor and Sackler Foundation Scholar there. He

received the 1958 Nobel Prize in Medicine for studies on the exchange of genetic material in bacteria and the U.S. National Medal of Science in 1989. Dr. Lederberg was a professor of genetics at the University of Wisconsin and Stanford University School of Medicine before becoming president of The Rockefeller University in 1978. A member of the National Academy of Sciences since 1957 and a charter member of its Institute of Medicine, Dr. Lederberg has been active on many government advisory committees and boards and served as Chairman of the President's Cancer Panel from 1979 to 1981. Dr. Lederberg received his B.A. from Columbia College, was a medical student at Columbia University College of Physicians and Surgeons, and obtained his Ph.D. from Yale.

**Dr. Sheila M. McGuire**

Dr. McGuire is president of the Iowa Health Research Institute and an expert in the epidemiology of oral diseases, geriatrics research, and fluoride research. A former Assistant Professor in the Harvard Medical School's Department of Dental Care Administration and adjunct faculty member at the University of Iowa College of Dentistry, Dr. McGuire was a member of the Health Professionals Review Group for the White House Task Force on National Health Care Reform. She also served a two-year term as chair of the Massachusetts Public Health Association's Legislative Committee. Dr. McGuire received her Doctor of Dental Surgery degree from the University of Iowa; her Master's in Epidemiology from the Harvard School of Public Health; and her Doctorate of Medical Sciences in Epidemiology from Harvard.

**Dr. David Rall**

Dr. Rall is the former Director of the National Institute of Environmental Health Sciences (NIEHS) and is one of the world's leading authorities on toxicology and environmental health. He was the founding Director of the National Toxicology Program, the largest toxicity testing program in the world, and has authored and co-authored approximately 170 papers relating to comparative pharmacology, cancer chemotherapy, pesticide toxicology, drug research and regulation, among other topics. Dr. Rall has served on and/or chaired numerous interagency and international committees on toxicology and environmental health, and now is serving as foreign secretary for the National Academy of Science's Institute of Medicine. Dr. Rall received his B.S. degree from North Central College and his M.S. and Ph.D. degrees in Pharmacology, as well as his M.D. degree, from Northwestern University.

**Dr. Virginia V. Weldon**

Dr. Weldon is Senior Vice President, Public Policy, for Monsanto Company. Her overall responsibilities include identifying public policy issues affecting the company, setting priorities, and implementing Monsanto's approach to these issues. Prior to joining Monsanto in 1989 as Vice President, Scientific Affairs, Dr. Weldon was a professor of pediatrics, deputy chancellor for

medical affairs, and vice president of the Medical Center at Washington University School of Medicine and Medical Center. She is a member of the President's Committee of Advisors on Science and Technology, and a distinguished service member of the Association of American Medical Colleges,
whose assembly she chaired in 1985-86. Dr. Weldon received her A.B. degree from Smith College and her M.D. degree from the State University of New York at Buffalo.

**Dr. Gail Charnley**, Executive Director.

Dr. Charnley has 20 years of experience in environmental toxicology and risk assessment, including laboratory research focusing on the role of environmental factors in human cancers. She was most recently acting director of the toxicology and risk assessment program at the National Academy of Sciences, where she served as project director of several committees convened to evaluate methodologic questions related to evaluating human health effects from chemical exposures. She has performed health risk assessments and developed regulatory criteria for human exposure to environmental contaminants for a variety of regulatory agencies and has chaired several U.S. Army Science Board committees. She currently serves as a councilor of the Society for Risk Analysis. Dr. Charnley received her A.B. in Biochemistry from Wellesley College and her Ph.D. in Toxicology from the Massachusetts Institute of Technology.

# Appendix A.2

# Mandate of the Commission on Risk Assessment and Risk Management

**United States Environmental Protection Agency**
**Advisory Committee Charter**

## Risk Assessment and Management Commission

1. PURPOSE. This charter renews the Risk Assessment and Management Commission in accordance with requirements of the Federal Advisory Committee Act, 5 U.S.C. App. 2, §9(c).

2. AUTHORITY. The Commission was specifically directed under Section 303 of the Clean Air Act, as amended onNovember 15, 1990.

3. OBJECTIVE AND SCOPE OF ACTIVITY. As required by the Clean Air Act Amendments of 1990, the Risk Assessment and Management Commission shall make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances.

The Commission shall consider:

(a) The report of the National Academy of Sciences authorized by section 112(0) of the Clean air Act, the use and limitations of risk assessment in establishing emissions and effluent standards, ambient standards, exposure standards, acceptable concentration levels, tolerances or other environmental criteria for hazardous substances that present a risk of carcinogenic effects or other chronic health effects and reductions in the number of persons exposed at various levels of risk, the incidence of cancer, and other public health factors;

(b) The most appropriate methods for measuring and describing cancer risks or risks of other chronic health effects from exposure to hazardous substances considering such alternative approaches as the lifetime risk of cancer or other effects to the individual or individuals most exposed to emissions from a source or sources on both an actual and worst case basis, the range of such risks, the total number of health effects avoided by exposures standards, acceptable concentration levels, tolerances and other environmental criteria, reductions in the number of persons exposed at various levels of risk, the incidence of cancer, and other public health factors;

(c) Methods to reflect uncertainties in measurement and estimation techniques, the existence of synergistic or antagonistic effects among hazardous substances, the accuracy of extrapolating human health risks from animal exposure data, and the existence of

unquantified direct or indirect effects on human health in risk assessment studies;

(d) Risk management policy issues including the use of lifetime cancer risks to individuals most exposed, incidence of cancer, the cost and technical feasibility of exposure reduction measures and the use of site specific actual exposure information in setting emissions standards and other limitations applicable to sources of exposure to hazardous substances; and

(e) Comment on the degree to which it is possible or desirable to develop a consistent standard of acceptable risk, among various Federal programs.

4. FUNCTIONS. (a) In the conduct of the studies required by this section, the Commission is authorized to contract (in accordance with Federal contract law) with nongovernmental entities that are competent to perform research or investigations within the Commission's mandate, and to hold public hearings, forums, and workshops to enable full public participation.

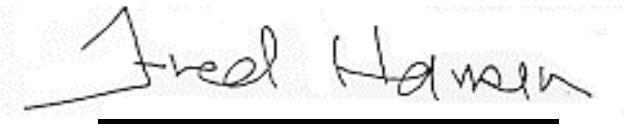
(b) The Commission may appoint and fix the pay of such staff as it deems necessary in accordance with the provisions of title 5, United States code. The Commission may request the temporary assignment of personnel from the Environmental Protection Agency or other Federal agencies.

(c) The members of the Commission who are not officers or employees of the United States, while attending conferences or meetings of the Commission or while otherwise serving at the request of the Chair, shall be entitled to receive compensation at a rate not in excess of the maximum rate of pay for Grade GS 18, as provided in the General Schedule under section 5332 of title 5 of the United States Code, including travel time, and while away from their homes or regular places of business they may be allowed travel expenses, including per them in lieu of subsistence as authorized by law for persons in the Government service employed intermittently.

(d) A report containing the results of all Commission studies and investigations under this section, together with any appropriate legislative recommendations or administrative recommendations, shall be made available to the public for comment not later than 42 months after the date of enactment of the Clean Air Act Amendments of 1990 and shall be submitted to the President and to the Congress not later than 48 months after such date of enactment. In the report, the Commission shall make recommendations with respect to the appropriate use of risk assessment and risk management in Federal regulatory programs to prevent cancer or other chronic health effects which may result from exposure to hazardous substances.

5. COMPOSITION AND MEETINGS. The Commission shall be composed of ten members who shall have knowledge or experience in fields of risk assessment or risk management, including three members to be appointed by the President, two members to be appointed by the Speaker of the House of Representatives, one member to be appointed by the minority Leader of the House of Representatives, two members to be appointed by the Majority Leader of the Senate, one member to be appointed by the Minority leader of the Senate, and one member to be appointed by the President of the National Academy of Sciences. Meetings will be held as necessary. A full-time employee of the Environmental Protection Agency has been assigned as the Designated Federal Officer, who will be present at all meetings and is authorized to adjourn any meeting whenever it is determined to be in the public interest. The estimated annual operating cost of the Commission for FY94 was approximately $48,976.38, which includes .35 FTE work year of staff support. This figure will. increase in FY95 once the Commission hires it's staff, meets on a monthly basis for a year, obtains office space, etc. The Office of the Administrator oversees and executes the budget assigned to the Commission and the office of Air provides administrative support as provided by the Clean Air Act Amendments of 1990.

6. DURATION. The Commission shall cease to exist upon the date determined by the Commission, but not later than 9 months after the submission of such report.



NOV 14 1994
Agency Approval Date

Deputy Administrator

NOV 15 1994
Date Filed with Congress

# Appendix A.3

# Comments on
# *Science and Judgement in Risk Assessment*

# Comments on the Conclusions of *Science and Judgment in Risk Assessment*

The primary message of *Science and Judgment in Risk Assessment*, the 1994 National Research Council (NRC) report to the Environmental Protection Agency (EPA) was that although EPA's health-risk assessment methods were fundamentally sound, it needed to establish more clearly the scientific and policy basis for those risk assessments and describe the uncertainties and variabilities associated with health risk estimates. This appendix reviews the NRC report's primary conclusions in science, policy, and uncertainty and comments on them in the context of the Commission's mandate.

## 1. Uses and Limitations of Risk Assessment

The NRC report emphasized that risk assessment is a set of tools and that it should be an adjunct to the primary regulatory goal of safeguarding public health, not an end in itself. Health risk assessment is but one element of environmental decision-making—a component of decisions about whether, how, and to what degree the assessed risk requires reduction. The factors that might be considered by decision-makers depend on the requirements of applicable statutes, precedents established within the responsible government agencies, and good public policy. The limited resources available for environmental protection should be spent to generate information that helps risk managers to choose the best possible course of action among the available options.

The Commission agrees that risk assessment is but one of a number of risk-management decision-making tools. The results of a risk assessment are not scientific estimates of actual risk; they are conditional estimates of the risk that could exist under specified sets of assumptions and—with political, engineering, social, and economic information—are useful for guiding decisions about risk reduction. The risk-management decision-making framework that is discussed in section 2 of the Commission's report provides guidance for including those kinds of information in risk-management decisions.

## 2. Maximal Use of Scientific Information versus Plausible Conservatism

The NRC report stated that EPA operates in a decision-making context that imposes pressures on the conduct of risk assessments and that these contextual pressures have led to recurrent problems of scientific credibility. Criticisms of EPA's risk assessments focus on three basic decision-making structural and functional problems:

- Unjustified conservatism, often manifested as unwillingness to accept new data or abandon default options.

- Undue reliance on point estimates generated by risk assessment.

- Lack of appropriate conservatism due to failure to accommodate such issues as synergism, human variability, unusual exposure conditions, and ad hoc departures from established procedures.

The NRC report pointed out that whereas EPA's risk-assessment practices rely heavily on default options, EPA has never articulated the scientific or policy basis of those options. Because of limitations on time, resources, scientific knowledge, and available data, however, the report concluded that EPA should generally retain its conservative, default-based approach to risk assessment for screening analysis in standard-setting. The authors offered several recommendations to make this approach more effective:

- Use an iterative approach to risk assessment.

- Provide justification for defaults and establish a procedure that permits departure from defaults.

- When communicating information about risks to decision-makers and the public, identify the sources and magnitude of the uncertainty associated with risk estimates.

The Commission concurs that default assumptions are a necessary part of the conduct of risk assessments. Risk assessments make predictions about the unknowable by using inferences that have not been or cannot be adequately tested with the scientific method. In the absence of adequate scientific information, science- and policy-based assumptions are appropriate. The Commission also supports the goal of transparency and believes that assumptions used in risk assessments and the uncertainty associated with their results should be clearly identified and justified.

An iterative approach to risk assessment also seems reasonable. An iterative approach would start with relatively inexpensive screening techniques and move to more resource-intensive data-gathering, model construction, and model application as the particular situation warranted. To guard against the possibility of underestimating risk, screening techniques must be constructed to err on the side of caution when there is uncertainty. In many situations, for example, gathering site-specific exposure information or investigating the human relevance of a particular toxicologic end point observed in rodents can reduce the extent to which default assumptions are required. Screening risk assessments that use assumptions instead of site-specific information might be used to set priorities by identifying the sites that are likely to pose the greatest risks to health or the environment. More refined risk assessments that use more sophisticated information could then be performed on the riskier sites to obtain better risk estimates. Such an iterative approach is intellectually satisfying.

However, the Commission is concerned about the possible public reaction to iterative determinations of risk. Suppose that a first-tier, screening risk assessment of a contaminated

site concludes that an upper-bound incremental lifetime cancer risk greater than $10^{-6}$ is possible. Later refined risk assessments of the same site conclude that the risk is likely to be less than $10^{-6}$. The residents of the surrounding community have been told first that the site poses a risk to their health and now that it does not. It is unlikely that such apparently conflicting conclusions will establish any credibility for the regulatory agency or other organization that has announced them. Citizens will remain suspicious and will probably believe that the site constitutes a health hazard, despite messages to the contrary.

Nonetheless, the NRC report concluded that neither the resources nor the necessary scientific data exist to perform a full-scale risk assessment on every potentially hazardous chemical. Nor, in many cases, is such an assessment needed. There might be a vast difference between having "the truth" and having enough information to enable a risk manager to choose the best course of action from the options available. The latter criterion is more applicable in a world with resource and time constraints. Determining whether "enough information" exists to support a decision implies the need to evaluate a full range of decisions. Further improvement of a risk-assessment estimate might or might not be the most desirable course in a given situation, especially if the refinement is not likely to change the decision or if disproportionate resources have been directed to studying the risk at the expense of creating a full set of decision options from which to choose.

Using an iterative approach thus could yield the risk-management decisions required under regulatory mandates in a resource-sensitive manner and at the same time provide incentives for further research without the need for costly case-by-case evaluations. But communicating iterative estimates of risk to the public without loss of credibility will require serious consideration.

### 3. Inter-agency and Intra-agency Consistency

The NRC report observes that it often seems safest for a regulatory agency to take refuge in established procedures even if they have begun to appear scientifically outdated. External pressures, such as the demands of state agencies for precise guidance, strengthen this tendency. These managerial problems are faced by any regulatory body that is responsible for rendering consistent decisions based on changing scientific knowledge. To remain accountable to the public, regulatory agencies must assess uncertain science in accordance with principles that are fully and openly articulated and applied in a predictable and consistent manner from case to case. Science-policy rules might ensure a valuable degree of consistency from one case to another, but they do so in part by sometimes failing to stay abreast of changing consensus in the scientific community. Bureaucratic considerations of consistency can sometimes override good scientific judgment.

The NRC report concluded that there is a need for a tradeoff between flexibility on the one hand and predictability and consistency on the other regarding departure from default options. Agencies should seek a middle path between inflexibility and ad hoc judgments, but steering this course is difficult. Consistency and predictability are served if an agency sets out criteria

for departing from its guidelines. If such criteria are themselves too rigidly applied, the guidelines could ossify into inflexible rules; but without such criteria, the guidelines could be subverted at will with the potential for political manipulation of risk assessment.

Appendix A.6 of the Commission's report surveys risk-related consistency issues both within EPA and among several regulatory agencies. The survey notes that differences in how risks are calculated and how risk-assessment results are used in regulatory decision-making have evolved in different agencies and programs for a variety of reasons. Some of those differences are necessary because of the differing mandates or goals of the various programs, but risk-assessment and risk-management practices are in general poorly coordinated. Better coordination is needed to resolve inappropriate inconsistencies in situations in which two or more agencies regulate similar health or ecologic hazards. Some inconsistencies might be appropriate, however, in light of each agency's or program's own goals and mandates.

4. Bright Lines

In its discussion of bright lines, the NRC report concluded that judicial review has not established any particular method for EPA to use in determining what level of risk should be considered negligible. EPA in turn has decided that it cannot use any single metric as a measure of whether a risk should be considered negligible. Instead, it has adopted a general presumption that a lifetime excess risk of cancer of about one in 10,000 ($10^{-4}$) for the most exposed person constitutes negligible risk and that the margin of safety should reduce the risk for the greatest possible number of persons to an individual lifetime excess risk no higher than one in 1 million ($10^{-6}$). Such factors as incidence, the distribution of risks, and uncertainties are taken into account in applying those benchmarks.

The 1990 amendments to the Clean Air Act require that standards be set for emission sources if maximum achievable control technology allows a residual risk of greater than $10^{-6}$ to the person most exposed to emissions (the "maximally exposed individual", or MEI). Although that requirement appears to be an example of legislating risk-management decisions on the basis of the MEI, the $10^{-6}$ criterion in fact need be interpreted only as an upper-limit screening device. In addition, those standards need not be expressed in terms of quantitative risk. EPA *may* use the $10^{-6}$-$10^{-4}$ approach described above, but it is not required to do so. Any method that is consistent with the requirement that the standards provide an "ample margin of safety" and reduce risk to a level judged acceptable by EPA may be used.

As discussed in section 5.3 of the Commission's report, the Commission does not support legislating reliance on specific bright lines for environmental regulatory decision-making, except as guideposts or goals for decision-making. If numerical targets are to be included in agency rules, the Commission prefers the use of ranges between bright lines as goals, which would permit flexibility in decision-making that reflects uncertain risk estimates, uncertain cost estimates, and local stakeholder preferences. Decision-makers should be expected to apply bright line ranges flexibly, such as using $10^{-6}$ as a benchmark for screening risk assessments, but not as a yes-or-no criterion for site cleanup decisions. Specific bright lines

should not be mandated by Congress—they should be established, when appropriate, by regulatory agencies. Congress should continue to use qualitative language in legislation, such as "reasonable certainty of no harm".

5. Peer Review

The NRC report recommended that peer review, workshops, and other devices be used to ensure broad peer and scientific participation and guarantee, as much as possible, that EPA's risk-assessment decisions are made with access to the best science available. It also recommended that EPA continue to rely on its Science Advisory Board and other expert bodies to determine when departing from a default option is warranted.

The Commission goes further in its recommendations about peer review, noting that peer review has not been used to evaluate the use of scientific or other technical information in regulatory policy and that there is no process for evaluating the effectiveness of peer review. The economic information used in regulatory policy is seldom peer-reviewed, and most agencies do not have official guidelines or policies for peer review. The Commission recommends several remedies for those problems while cautioning that the level of peer review should be commensurate with the importance or impact of the decision to be made. Peer review should not be used to stall the decision-making process.

6. Comparative Risk

The NRC report concluded that EPA should pay more attention than it now does to the appropriateness of various procedures for risk comparison. A scientifically sound way to do that would be to modify risk-assessment procedures to characterize more specifically the uncertainties in each comparison of risks—some larger, some smaller than the uncertainties in individual risk assessments. Because of the substantial and varied degrees of model and parameter uncertainties in risk estimates, it is almost impossible to rank relative risks accurately unless the uncertainty in each risk is quantified or otherwise accounted for in the comparison. If comparison of risks is imperative for regulatory purposes, the report suggested attempting to compute the uncertainty distribution of the ratio of two risks and choosing from it one or more appropriate summary statistics.

The Commission has addressed comparative risks from the perspectives of both risk communication and of conducting comparative risk projects for priority-setting. The Commission recommends that risk comparisons for risk communication help to convey the nature and magnitude of a particular risk estimate and be restricted to comparisons of risks associated with chemically related agents, different sources of exposure to the same agent, different kinds of agents with the same exposure pathway, and different agents that produce similar effects. The Commission also agrees that the appropriateness of procedures used to compare risks for priority-setting requires attention and evaluation and suggests that comparative risk-ranking paradigms are appropriate for guiding resource-allocation decisions.

7. Exposure Assessment

The NRC report noted that EPA has traditionally characterized exposure according to two criteria: exposure of the total population and exposure of a specified highly or maximally exposed individual (MEI). The MEI's exposure is estimated as the plausible upper bound of the distribution of individual exposures. The reason for finding the MEI, as well as population, exposure is to assess whether any individual exposure might occur above a particular threshold that, as a policy matter, is considered important. In its most recent exposure-assessment guidelines, EPA no longer uses the term MEI, noting the difficulty in estimating it and the variety of its uses. The MEI has been replaced with two other estimators of the upper end of the individual-exposure distribution, a "high-end exposure estimate" (HEEE) and the theoretical upper-bounding estimate (TUBE). The HEEE is not specifically defined ("the Agency has not set policy on this matter"), but it is a value in the upper tail of the individual-exposure distribution. The HEEE is based on the estimation of the distribution of exposures that people might actually encounter; from the individual exposures, it is possible to develop population exposure (and risk) distributions and include uncertainty estimation and personal-activity patterns. The exact percentile that should be picked for the HEEE is not specified, but it should be chosen to be consistent with the population size in a particular application. The TUBE is a calculated value that is expected to exceed the exposures experienced by all individuals in the actual distribution. Neither the HEEE nor the TUBE is explicitly related to the MEI.

The NRC report recommended that the underlying assumption that calculated exposure estimates are conservative be reaffirmed; if it is not, alternative exposure models whose performance has been clearly demonstrated to be superior should be used in exposure assessment. Those alternative models should be chosen to provide more accurate, scientifically founded, and robust estimates of pollutant-exposure distributions (including variability, uncertainty, and demographic information).

The Commission believes that the results of an exposure assessment can be a source of greatest uncertainty in a risk assessment and agrees that there is a need for more accurate, scientific, and validated models for exposure assessment. EPA should move away from estimates of exposure that are based on a mythical overexposed individual, which are likely to overestimate the exposures of most of the population and underestimate the exposures of special populations, such as subsistence fishermen. Point estimates of exposure convey no information about the extent to which they overestimate or underestimate exposures, and they should be used only for screening risk assessments. The entire distribution of a population's exposure concentrations should be used for more refined risk assessments, rather than just the exposures of a highly exposed subpopulation (although highly exposed populations, if they exist, should be identified and evaluated separately).

8. Differences in Susceptibility

The NRC report points out that EPA and the research community have thought almost

exclusively in terms of the bimodal type of variation, with a normal majority and a hypersusceptible minority. That model might be appropriate for noncarcinogenic effects, but it ignores a major class of variability with regard to cancer (the continuous, "silent" variety), and it fails to capture some bimodal cases in which hypersusceptibility might be the rule, rather than the exception. EPA's 1986 cancer risk-assessment guidelines, however, are silent regarding person-to-person variations in susceptibility and thereby treat all humans as identical, despite substantial evidence and theory to the contrary. That is an important "missing default" in the guidelines. The NRC report recommended that EPA adopt an explicit default assumption for susceptibility and that the magnitude and extent of human variability due to particular acquired or inherited cancer-susceptibility factors be determined through molecular epidemiologic and other studies. Results of the research should be used to adjust and refine estimates of risks to individuals and estimates of expected incidence in the general population. In addition, EPA should continue and increase its efforts to validate or improve the default assumption that, on average, humans to be protected at the risk-management stage have susceptibility similar to that of humans included in relevant epidemiologic studies, the most sensitive rodents tested, or both. EPA's 1996 *Proposed Guidelines for Carcinogen Risk Assessment* mention the importance of including information on susceptibility differences when available, but do not go so far as recommending an explicit default assumption.

The Commission agrees with the NRC report's conclusions regarding susceptibility. Risk assessments should be conducted so that populations with a special susceptibility or risk—whether because of greater exposures than the general population, because of other concurrent exposures, or because of some physiologic characteristic that increases sensitivity—are identified and the extent to which they are at greater risk determined.

9. Multipathway, Multisource, and Mixture Exposures

EPA currently adds the risks related to each chemical in a mixture to develop a risk estimate for that mixture. That approach is based on an assumption that doses of different agents can be treated as roughly additive with regard to inducing the end point; this assumption is reasonably consistent with much of the experimental evidence on the joint actions of chemicals in mixtures. The NRC report concluded that this additivity procedure is generally appropriate when the only risk characterization needed is a point estimate for use in screening. The Commission agrees that dose additivity of mixture components is an appropriate assumption for most cases, but it believes that the issue of dose additivity versus response additivity has not been adequately addressed.

The NRC report also concluded that any comprehensive assessment of health risk associated with environmental exposure to any particular compound must consider all possible routes by which people might be exposed to that compound, even if expected applications in risk management are limited to some particular medium or source. The report recommended that EPA consider using appropriate statistical procedures to aggregate cancer risks associated with exposure to multiple compounds. Aggregating risks associated with different exposures might not be possible, however, because the analyses for each exposure will produce risk estimates

of differing accuracy and conservatism. The Commission agrees that procedures for aggregating risks must be explored. The issue of which end points or exposures can be aggregated appropriately is complex—for example, should different tumor types within the same organ or tumors in different organs be aggregated, or do these constitute different, independent responses? Considering multiple sources of contaminant exposure is particularly important in the context of environmental justice and identifying sensitive populations requiring special consideration, and methods to do so are needed.

10. Uncertainty

The NRC report concluded that it might be undesirable to reduce a risk characterization to a single number, or even to a range of numbers intended to portray uncertainty. Instead, the report recommended that EPA consider giving risk managers risk characterizations that are both qualitative and quantitative and both verbal and mathematical. The Commission concurs that better communication about risk-related uncertainty is needed, and it encourages regulatory agencies to explain the uncertainty associated with any numerical estimates of risk and to eliminate risk estimates with phony accuracy (e.g., $4.237 \times 10^{-5}$), which communicate a misleading confidence in accuracy. The Commission also believes that risk characterizations for routine risk assessments should emphasize qualitative information about risks more than quantitative information. Qualitative information is likely to be more understandable and useful than quantitative estimates or models to risk managers and the public. Qualitative information includes a careful description of the nature of the potential health effects of concern, of the strength and consistency of the evidence that supports an agency's classification of a chemical or other exposure as a health hazard, and of any means to prevent or reverse the effects of exposure.

The NRC report also concluded that any expression of probability regarding model uncertainties (i.e., inability to determine which scientific theory is correct or what assumptions should be used to derive risk estimates), whether qualitative or quantitative, is likely to be subjective. Subjective quantitative probabilities could be useful in conveying the judgments of individual scientists to risk managers and to the public, but the process of assessing subjective probabilities is difficult and essentially untried in a regulatory context. Substantial disagreement and misunderstanding about the reliability of quantitative probabilities could occur, especially if their basis is not set forth clearly and in detail.

As discussed in section 3.3 of the Commission's report, the Commission believes that, although there is general agreement as to the value of qualitative statements describing critical uncertainties in a risk assessment, there is opposition to the use of a more routine and formal mathematical approach to characterizing uncertainties. The opposition is based on the belief that a formal, quantitative approach is unnecessary, is difficult to perform, and will not improve risk communication. Uncertainty is inherent in any estimation procedure. Some sources of uncertainty, such as those related to estimating exposures, are likely to be relatively easily addressed through the use of statistical methods. Other types of uncertainty, such as those associated with species-to-species or high-to-low dose extrapolation, are less

straightforward or quantifiable. Characterizing the uncertainty and variability that underlie a potential risks can generate a distribution of risks, instead of a point estimate, but it should be kept in mind that when data are scarce, assumptions about the underlying shape of a distribution will be needed—that is, when uncertainty is greatest, a range of probabilities based on assumptions would replace point estimates based on assumptions.

Providing a numerical range of risk estimates reflecting uncertainty and variability might allow decisions to be made in a more informed and more transparent manner than is possible when only a single point estimate is generated. However, communicating a range of risk estimates might be misconstrued by those unfamiliar with quantitative methods as implying that all the numbers in the range are equally likely or plausible and are therefore equally valid for regulation. Many risk assessments are crude yardsticks for decision-making. In this context, the routine provision of a range of risk estimates might only confuse and delay the regulatory process.

# Appendix A.4

# Individuals Who Presented Testimony at Commission Meetings

# Speakers at Commission Meetings

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California Association of Sanitation Agencies

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Manager of Air Quality planning,
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Walter Buchholtz
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Paul Chrostowski
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U.S. Environmental Protection Agency

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U.S. Consumer Product Safety Commission

Josephine Cooper
Vice President
Environment and Regulatory Affairs
American Forest and Paper Association

Bertram Cottine
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Michael Dourson
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Toxicology Excellence for Risk Assessment

Kay Drey
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Jerry Fitzgerald English
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Brian Ferguson
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Legislative Director and Press Secretary
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# Appendix A.5

# Abstracts of Reports Prepared at the Invitation of the Commission

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**To obtain copies of the complete reports, circle those desired and facs to 202-233-9540 with your name, address, and phone written below, or obtain them over the internet at the *RiskWorld* website, http://www.riskworld.com, after they become available on July 1, 1996.**

# A Survey of Methods for Chemical Health Risk Assessment among Federal Regulatory Agencies

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According to its charter, the National Commission on Risk Assessment and Risk Management is charged with investigating "the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws." The demands of the risk assessment process far outstrip the ability of scientific investigation to give firm answers. Environmental statutes, however, place responsibility on certain Federal agencies to set regulatory limits on human exposure to potential environmental toxins so as to ensure public safety. The practical need remains, then, to make characterizations of the risk consequences (including the uncertainty about those consequences) of various potential actions. Faced with this practical problem, regulatory agencies have arrived at practical methodology. This methodology includes reliance on procedures that, while attempting to embody information from the available data, of necessity rely on uncertainty-bridging principles derived from a combination of general knowledge about chemicals, their behaviors in the environment and their toxic effects, a desire to maintain internal case-by-case consistency in how uncertainties are resolved, and a desire to ensure that regulatory decisions are likely to fulfill the legislative mandates about public health protection.

On the broad scale, Federal risk assessment practices follow the structure and methodological recommendations of the 1983 National Academy of Sciences report *Risk Assessment in the Federal Government: Managing the Process*. In detail, however, current practices in these areas vary among Federal agencies and even among regulatory programs within the EPA, reflecting the lack of a single, agreed-upon scientific procedure for the assessment of health risks from chemical exposures. In part, the diversity of methods can be attributed to the different questions being asked of the risk assessment process in different regulatory contexts by different environmental statutes. In part, it reflects different institutional judgments about the most appropriate methods and different scientific judgments about matters with high scientific uncertainty. And in part. it reflects simple policy choice made for the sake of consistency within each organization (which, owing to independent histories, becomes inconsistent among organizations). The effect of this diversity is to make it difficult to compare risks, or the actions taken to mitigate those risks, from one regulatory program to another.

The present report comprises a survey of chemical health risk assessment methodology among the Federal agencies primarily charged with regulating the production, use, emissions, and disposal of potentially toxic chemicals. The primary focus is on differences in standard methodology for assessment of potential chemically induced chronic health effects, examined in the context of each group’s legislative mandates. The groups included are the Food and Drug Administration (Center for Food Safety and Applied Nutrition), the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the Environmental Protection Agency, with special attention given to the various regulatory programs within the last agency. In conducting this survey, each regulatory program's enabling legislation—the statutes that mandate regulatory activity—was examined regarding legislative purposes, mandates, and the nature of the regulatory powers granted as they affect the conduct of risk assessment by particular groups. Special attention is focused on the laws' requirements about who in the exposed population is to be protected, how the distribution of exposures among people comes into play, and how sufficiently protective standards are defined. Each organization's principal documentation on risk assessment policy and methodological guidance

was examined. Many of the specific procedures are not clearly codified, however; office-specific practices are to be found in the patterns of analyses used in particular cases as documented in specific rulemaking actions. To develop information on these practices, and to gain a perspective on the operation of each regulatory office and its activities, a series of interviews was conducted with 23 key officials, risk assessors, and scientists in each of the offices covered by this survey.

Many of the methods of quantitative risk assessment, in the face of usually incomplete case-specific data, make conservative assumptions, on the grounds that "worst-case" analyses will at least not underestimate the true human risks. An application of the worst-case principle that has received considerable attention is the emphasis on risks calculated for the "maximally exposed individual" or MEI. The notion is that, in order for a regulatory action to protect the entirety of an exposed population, it must protect the person with the most exposure; hence, the most exposed person's potential risk serves as a benchmark for the adequacy of a proposed strategy to control, restrict, or ameliorate environmental concentrations of a chemical agent. The questions arise how often in current EPA practice and policies does the risk to the MEI actually form the basis of a regulatory decision and whether any such use follows from specific mandates in the regulatory statutes. Accordingly, particular attention is focused on the question of how various programs characterize exposure, on how individual risk versus population risk play in setting regulatory levels, and in particular on the role of estimates of the high end of individual exposure in this process.

The results of the survey are presented in discussions of each regulatory program's practices. Within the discussion of each program are sections on the program's enabling legislation and its risk mandates, notes on implementation of these mandates, and discussions of program-specific issues in hazard identification, dose-response analysis and characterization of quantitative potency, exposure assessment, and risk characterization and regulation. The main differences among agencies and EPA regulatory programs are summarized in tabular form.

To a large degree, the body of environmental laws that seek to establish practices that will ensure safety (or at least mitigate risk) of chemical exposures were established before risk assessment was a well recognized and codified discipline. Most of the methodology of risk assessment has been invented in reaction to the calls by these laws to define limits on exposure that will "protect the public health" or lead to "a reasonable certainty of no harm." That is, in passing the laws, Congress called on the regulatory agencies to develop means to assess risks so as to define exposure levels that would achieve the stated qualitative goals of health protection. The presumption in this approach (which is not always borne out) is that there will be relatively few such exposures in need of control and that controls that are clearly sufficient to achieve protection can be had at reasonable cost to those responsible and to society as a whole.

The present report has attempted to examine the major environmental laws for their mandates on risk and for their calls for risk assessment to address these mandates. Since the laws largely precede risk assessment methodology, there is little call for specific analytical actions on the part of regulatory agencies. Nonetheless, the need for risk assessment is

implicit in every call to define levels of exposure in regard to the potential health effects they may cause.

The different risk mandates are all rather vaguely worded, and it is not possible to discern calls for different methods of risk estimation from a mandate to assure "reasonable certainty of no harm" and one to "protect the public health with an adequate margin of safety." The chief difference among mandates is whether they call for balancing costs and benefits or whether they account for feasibility of controls, issues that affect the uses to which assessed risks are to be put in regulation but that do not affect the conduct of risk estimation itself. Only in the Consumer Product Safety Act are the criteria for balancing risks and benefits, and the particular findings in this regard that must be made to justify regulation, explicitly spelled out.

The environmental laws do not allow the regulatory agencies any action to control risks—they specify the nature of the regulatory actions to be undertaken, whether these be the issuance of permits or registrations, the definition of acceptable ambient concentrations, the limitations of discharges, and so on. The nature of the regulatory actions required vary more among laws than do the risk mandates, and the regulatory powers under each law are tailored to the nature of the regulated enterprise or activity, hinging largely on practical questions regarding where regulatory control can be effectively administered to accomplish the ends and purposes intended.

From the point of view of risk assessment, this variation in regulatory powers tends to manifests itself in different exposure assessment methods. Consequently, there is more variation among regulatory agencies and programs in exposure assessment methods procedures than in assessment of toxic effects. In this report, an attempt has been made to relate the methods used in risk assessment (and in particular, exposure assessment) to the nature of the law's regulatory activities. Given these differences in the regulatory powers granted by the various laws, it is unreasonable to expect exposure and risk assessments to be equally realistic across regulatory groups. By their nature, laws acting through permits will define exposures above those usually seen in compliance since they regulate by specifying maxima; laws acting through ambient concentration standards that represent ambitions to control pollution will define exposures below those typically seen, since they regulate by specifying goals to be striven for; and laws acting through specification of difficult to achieve technical controls will define exposures (or at least emissions) close to that actually achieved, since they act by imposing uniformity in control.

Some regulatory activity must be prospective, aiming at controlling potential risks from activities yet to occur, while others focus on mitigation of current risky activity. Some laws empower regulators to require data on toxicity and exposure from petitioners, while in other settings risk analysts must make do with whatever existing data can be identified. Some laws permit regulatory control of many aspects of potentially risky activity, while others must allow for considerable unregulated variation in the public's activities regarding frequency, manner, and magnitude of exposure to compounds as a consequence of variation in lifestyles and preferences.

When the express aim of a law is to *manage* risks to the population, the exposure assessment should attempt to characterize the full distribution of exposure levels in the population as accurately as possible, so that the distribution of risks can be examined (and changes or shifts in the burden of risk under different regulatory options noted). In this circumstance, it is important to attend not only the existence of high individual risks, but also to the total burden of risk on the population. Many current environmental laws, however, are written so as to require *protection* from risk. Permits are issued, standards are set, conditions of use are defined, or cleanups are mandated so as to set limits on exposure such that few if any of the population of concern will experience risk levels that are "unacceptable." In this setting, the focus is on setting regulations to protect those at the high end of the risk distribution. This focuses the attention of the assessment on defining the upper end of the range of exposure scenarios for which it is intended to furnish protection. Depending on the law, this may be the top end of the actual distribution of exposures near a source (as in the Clean Air Act §112), a person of somewhat above average consumption of a medium contaminated up to a limit deemed permissible (as in the Safe Drinking Water Act), or an especially frequent consumer of a foodstuff containing an additive (as in the Federal Food, Drug, and Cosmetic Act). The present survey found much emphasis on high-end exposures and hypothetical exposures that would be the maximum allowable under a proposed regulation, but the only instance where a true "maximally exposed individual" serves as the basis of regulatory decision is in the Clean Air Act's provisions for triggering further risk analysis owing to "residual risk" after technical engineering controls on emissions have already been applied.

Whether the protected exposure is actual or hypothetical (and whether a hypothetical exposure is high or low compared to the upper end of actual exposures) may have less to do with data availability or willingness to use different exposure estimation techniques than with the intent of the law. A key factor is which parts of the exposure equation are under regulatory control and which are not. For instance, in setting pesticide tolerances, the assumption is made that all foods on which the agent is permitted in fact bear it, and at the maximally permissible level, when conducting initial exposure assessments. This is done not simple to be "conservative," but because the law requires setting levels that will be safe for consumers of the foods, and this must include protection of someone who chooses to eat all the foods containing the agent, even though few people may actually do so. Moreover, since permitting residues up to the tolerance level implies that such all such levels are acceptably safe, the tolerances have to be set such that they would be safe *if* they occur, irrespective of whether they in fact occur.

In other words, much of the attention to estimates of risk that are conservative in the face of uncertainty about potency and much of the focus on the upper end of exposures arise because these methods were invented to implement the calls from the statutes for defining regulatory actions that would ensure safety. As notions of effective risk management evolve, it is becoming clear that such methods are less well suited for estimating the actual burden of exposure and risk in populations. The discussions of each statute and regulatory program in this report attempts to examine how the methods that have evolved in each program reflect the tasks set for regulators, either explicitly or implicitly, by the various statutes as they set mandates about what is to be accomplished and by what regulatory actions.

The inconsistency of methods for dose-response assessment cannot be so easily explained in terms of response to different regulatory needs. The variety of methods seems to reflect the somewhat separate history of development of potency estimation in the different groups and the lack of a definitive scientific basis to guide these independent evolutions along exactly the same path. The variety of methods correctly reflects the uncertainty about the best or most appropriate procedures, but it results in the awkward result that different agencies can arrive at different characterizations of an agent's carcinogenic potency from the same set of data, based only on differences in preferred methods and precedents from earlier analyses. It would seem that harmonization of these methods to the extent achievable would be beneficial. At the same time, harmonization achieved through rigidity in rules for choice of methods would falsely imply that the mandated set of approaches is more correct than others and would stultify application of case-by-case judgment.

As with exposure assessment, the focus of much potency analysis is on defining levels of exposure that can be more or less assured of posing "acceptable" risk. The methods that are used in the face of uncertainty can usually be understood in this light. As the questions being asked by the risk management process move beyond such issues of assurance of safety, existing methodology and practices established in response to current environmental statutes become less appropriate.

Fundamentally, risk assessment methods are practical inventions put in place to address the kinds of questions asked of regulatory analysis by the mandates of the environmental laws. These laws and their mandates can be changed, and the methods for assessing risks will have to change with them, to respond to new needs.

# Health Risk Assessments Prepared per the Risk Assessment Reforms under Consideration in the U.S. Congress

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# 1 Summary

The Commission on Risk Assessment and Risk Management retained Cambridge Environmental Inc. to conduct case studies of health risk assessment that conform with proposed regulatory reform legislation[1] and to comment, as risk assessors, on the required methods. The principal relevant mandate in these legislative proposals is that the conservative point estimates of risk currently generated and relied upon be augmented with estimates that are in some sense "best" —that are central tendency estimates, generated by taking better account of the uncertainties and variabilities in the underlying data and assumptions.

To illustrate the techniques required to satisfy such a mandate, we studied four cases. The objective of the first case study was to estimate incremental lifetime risk of cancer to an individual in a population whose water supply had been contaminated with part-per-billion levels of 1,1-dichloroethylene (1,1-DCE). The second case study differed from the first only in that 1,1-DCE was allowed, consistent with its dose-response data, to have either an anticarcinogenic or a carcinogenic potency, rather than being constrained to have only a carcinogenic potency, as is the current regulatory norm. The third case study differed from the first only in that it considered exposure similar levels of vinyl chloride, a potent and known human carcinogen, rather than exposure to the equivocally carcinogenic 1,1-DCE. The fourth case study estimated incremental lifetime risk of cancer associated with occupational exposures, rather than low-level environmental exposures, to 1,1-DCE.

For each case study, we first estimated the incremental lifetime risk of cancer to a "reasonably maximally exposed individual" using the methods currently recommended by U.S. EPA. We then prepared a distribution of risk estimates by choosing parameter values for each variable from the distribution defined for that variable and combining these choices in the risk equation. These latter tasks required (1) significant research in the scientific literature, and (2) not a small amount of statistical and computational expertise, Using computer software we created, we repeated the risk calculation about 20,000 times, gathering up each estimate of incremental lifetime risk of cancer to define its distribution. From the distribution, we could estimate the mean, median and 95$^{th}$ percentile (and other statistics) of the distribution for the incremental lifetime risk of cancer. Each of these might be considered a "best" estimate of risk.

The results of the four case studies are summarized in the following table.

[1] In particular, bills S 343 and HR 1022.

Table 1. Statistics of the distributions of risk estimates from the case studies

| Case | Median (50th percentile) | Mean | 95th percentile | Current EPA-style point-estimate (reasonably maximum exposure) |
|---|---|---|---|---|
| 1,1-DOE, standard | $1.2 \times 10^{-9}$ | $1.6 \times 10^{-6}$ | $1.7 \times 10^{-6}$ | $1.3 \times 10^{-4}$ |
| 1,1-DOE, non-standard | $2.0 \times 10^{-9}$ | $9.5 \times 10^{-6}$ | $1.7 \times 10^{-6}$ | — |
| Vinyl chloride (standard) | $1.4 \times 10^{-6}$ | $8.8 \times 10^{-5}$ | $2.0 \times 10^{-4}$ | $4.1 \times 10^{-4}$ |
| 1,1-DOE workers | $1.4 \times 10^{-6}$ | $3.6 \times 10^{-3}$ | $8.4 \times 10^{-3}$ | $2.7 \times 10^{-2}$ |

Several comparisons are noteworthy. In the first case study, U.S. EPA methods (specifically, those used for risk assessment of Superfund sites) yielded a point-estimate of risk of $1.3 \times 10^{-4}$. Although such an upper-bound point estimate is typically assumed by many to be at about the 95$^{th}$ percentile of the risk estimate distribution, it corresponded here to the 99.8th percentile of such a distribution. The probabilistic method employed here found that the 95$^{th}$ percentile of the distribution was about 80-fold lower -- $1.7 \times 10^{-6}$. These two different estimates -- both upperbound -- would likely indicate dramatically different intervention strategies. Risks as high as the former often require extensive remediation, whereas risks as low as the latter usually do not.

The second case study, in which exposures to 1,1-DCE were allowed to confer either beneficial or detrimental effects on cancer risk, yielded two central tendency estimates of risk that were negative -- so suggested that low levels of 1,1-DCE might confer no excess risk of cancer, and might even confer a small benefit. Nonetheless, the 95$^{th}$ percentile of the distribution of risk estimates in the second case study was identical to that estimated in the first case study ($1.7 \times 10^{-6}$). Thus, allowing the relevant portions of the bioassay data themselves to define the slope and bounds of the dose-response curve -- as opposed to imposing standard, regulatory restrictions on that curve -- yielded both dramatically different central tendency estimates and identical upper-bound estimates.

The third case study, in which exposures to vinyl chloride were substituted for dose-equivalent exposures to 1,1-dichloroethylene, yielded a point estimate of risk ($4.1 \times 10^{-4}$) that was only three times larger than the point estimate generated in the first study for 1,1-DCE. Such a minor difference belies the substantial differences in the quality and quantity of data surrounding the

carcinogenicity of these two chemicals. In contrast, the probabilistic methods yield a 95$^{th}$ percentile estimate for the risks from vinyl chloride that is some 120-times larger than the estimate from 1,1-DCE.

Finally, the fourth case study suggested that (1) occupational exposures to 1,1-DCE were as expected, substantially riskier than low-level environmental exposures, and (2) that the point estimate of risk is only some three-fold larger than the 95$^{th}$ percentile estimate. Under certain circumstances, such as relatively high exposures, the deterministic and probabilistic methods may thus yield reasonably similar upper-bound estimates of risk.

Working through these case studies, we have reached certain conclusions about the proposed risk assessment reforms. Among these opinions are:

- **Performing risk assessment holistically and probabilistically is not easy**. Considerable research must be made into the ranges of plausible estimates for a vast number of inputs. Considerable quantitative expertise including computer-programming skills, are required to design and implement the method. The risk assessor must genuinely understand -- as opposed to merely use -- many sorts of models -- and perhaps be able to create some anew. He or she must combine distributions in valid manners.

- **Current point-estimates of risk may obscure underlying scientific complexities and other important information**. Public health policy demands upper-bound estimates of risk; but if these are calculated too crudely, they prevent efficient, health-protective decision-making.

- **Under various circumstances, probabilistic risk assessment may indeed be informative and worthwhile**. Techniques used to generate risk estimates should scale with the situation to be assessed. Some situations can be shown to be harmless under almost any method of risk analysis; running full Monte Carlo analyses on these would be inefficient. Other situations are much harder to call, have high stakes, or otherwise demand more sophisticated analysis. For such situations, probabilistic methods, carefully and honestly implemented, may offer the best current hope.

- **Health risk assessment is typically dominated by uncertainty, rather than by variability**. Distributions of estimates of health risk are remarkably broad; and most of that breadth is due to our fundamental uncertainty about the health effects of low-level exposures to environmental chemicals, not to variations in people's exposures. The high ends of a risk distribution are driven primarily by "pessimistic" interpretations of, but consistent with, the dose-response data. These data typically derive from over-exposed rodents whose responses may or may not predict human responses in the situation under analysis.

- **Central tendency, mean or median estimates of risk are unlikely to provide a full, useful basis for public health decision-making. One really needs the full distribution. However, a properly derived 95$^{th}$ percentile estimate of risk, supplemented with mean and median estimates, may provide a set of three bottom lines that can indeed be a basis for sound public policy.** There is no single estimator of risk appropriate to all situations, and the *definition* of the estimator matters greatly. Further, no matter what estimator of risk might be chosen, the estimate must be compared with some standard for decision-making, and that choice of standard is also crucial.

- **An entirely scientific risk assessment is a mirage. There is no single right way to do it.** Sound policy should indeed rest on sound science. But risk assessment is not and cannot be a wholly scientific undertaking. Risk assessment often turns upon details that are inherently unknowable. In general, probabilistic and holistic risk assessments could lead to improved decision-making. Whether such assessments prove to be more defensible than the *status quo* is harder to say.

# Cost-Benefit Analysis and Regulatory Reform

**Resources for the Future**
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# Cost-Benefit Analysis and Regulatory Reform

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## Executive Summary

The ongoing efforts in the 104th Congress to legislate requirements for cost-benefit analysis (CBA) and the revised OMB Guidelines for the conduct of such assessments during a regulatory rule making process, highlights the need for a comprehensive examination of the role cost-benefit analysis can play in agency decision-making. This white paper summarizes the state of knowledge and offers suggestions for improvement in the conduct and use cost-benefit analysis, especially in the context of environmental regulations. Its scope is not confined to assessments of cancer risks or other toxic substances concerns , but rather, addresses the entire range of environmental policy issues.

CBA is a technique intended to improve the quality of public policy decisions, using as a metric a monetary measure of the aggregate change in individual well-being resulting from a policy decision. Individual welfare is assumed to depend on the satisfaction of individual preferences, and monetary measures of welfare change are derived by observing how much individuals are willing to pay, i.e., willing to give up in terms of other consumption opportunities. This approach can be applied to nonmarket "public goods" like environmental quality or environmental risk reduction as well as to market goods and services, though the measurement of nonmarket values is more challenging. Cost-effectiveness analysis (CEA) is a subset of cost-benefit analysis in which a policy outcome (e.g., a specified reduction of ambient pollution concentration) is taken as given and the analysis seeks to identify the least-cost means for achieving the goal (taking into account any ancillary benefits of alternative actions as well).

To its adherents, the advantages of CBA (and CEA) include transparency and the resulting potential for engendering accountability; the provision of a framework for consistent data collection and identification of gaps and uncertainty in knowledge; and, with the use of a money metric, the ability to aggregate dissimilar effects, such as those on health, visibility, and crops, into one measure of net benefits. Criticisms of CBA hinge on questions about a) the assumption that individual well-being can be characterized in terms of preference satisfaction; b) the assumption that aggregate social well-being can be expressed as an aggregation (usually just a simple summation) of individual social welfare; c) the empirical problems encountered in quantifying economic value and aggregating measures of individual welfare.

We take a) as axiomatic, noting also that because CEA is a subset of CBA, philosophical objections to the use of a preference-based approach to individual welfare measurement apply equally to both. For b) we agree that CBA does not incorporate all factors that can and should influence judgments on the social worth of a policy, and that individual preference satisfaction is not the only factor. Nevertheless, we assert that CBA must be included as a key factor. Other arguments under c) are measurement problems -- how choices based on preferences permit can one to infer economic values in practice.

The state of the science of measuring such economic values is exceedingly active. Estimates of the willingness to pay for reductions in mortality and morbidity risks, for avoiding environmental damages to recreation opportunities, and for avoiding visibility degradation, are the most active and successful areas of valuation. Issues of a higher order stalk the estimation of nonuse values, and a variety of mostly empirical concerns have left materials damages poorly understood. Estimation of the costs of reducing environmental effects, while generally thought to be relatively straightforward, are found to be at least as challenging as estimating the benefits, although there are easy-to-estimate, but perhaps, poor proxies for the loss in social well-being such costs represent.

The white paper offers a number of suggestions to regulatory agencies in conducting CBA, drawing upon the "best practices" identified in the new OMB Guidelines. These include the use of clear and consistent baseline assumptions; the evaluation of an appropriately broad range of policy alternatives, including alternatives to new regulation; appropriate treatment of discounting future benefits and costs, and accounting for the cost of risk-bearing; the use of probabilistic analyses and other methods to explore the robustness of conclusions; the identification of nonmonetizable or nonquantifiable aspects of a policy, and the potential incidence of all effects; and, last but not least, the use of benefit and cost measures that are grounded in economic theory (i.e., measures of willingness to pay and opportunity cost).

The paper also argues that from an economic perspective, risk assessment is a subset of benefits analysis in that quantitative relationships between pollution exposure and some human or ecological response are needed to estimate the population response and thus the marginal change in welfare resulting from a policy. The culture of risk assessment is not generally oriented towards this role, implying that risk assessments do not always provide the necessary input to an economic benefits analysis. Suggested changes in risk assessment practices include: estimating population risks, not just individual risks; providing information on the entire distribution of risks, including central tendencies, rather than just upper-end risk measures based on conservative assumptions about the potential threat; providing as much information as is practicable about how risks vary with exposure, rather than just identifying "safe" or "acceptable" threshold levels of exposure; and considering substitution risks as of equal importance to direct risk reductions. Economists and risk assessors together must also address how to give appropriate attention to both lay perceptions and expert assessments of risks.

The improvements in the methodologies for estimating the costs and benefits of regulatory activities discussed above are necessary but not sufficient for significantly improving regulatory decisions. Several more overarching issues involving the role of cost-benefit analysis in public decisionmaking must also be debated and resolved. These include:

**Decision Rules and Cost-Benefit Analysis: While decisions should not be based solely on a simple cost-benefit test, a cost-benefit assessment should be one of the important factors in the decision.** This approach is entirely consistent with Executive Order 12866. A rule with negative measured net benefits could still be promulgated under this approach if it could

be shown that other factors (such as an improvement in the equity of the income distribution or an enhancement of environmental justice) justified the action. A discussion providing the justification would help ensure accountability.

**Quantifiable Benefits and Costs: CBA needs to have standing as a part of all major regulatory *and legislative* decisions.** In particular, CBA must have standing to implement the decision approach outlined above. Administrative reforms could accomplish much, but legislative changes will be needed to implement this suggestion where the use of CBA currently is precluded.

**Nonquantifiables and CBA:** We recommend a value of information approach. This involves estimating the net benefits for the quantifiable elements and asking how large the nonquantifiable elements would have to be to reverse the conclusion of the analysis or, as a broader measure, the regulatory decision. This provides information about nonquantifiables (beyond their enumeration and description) in a useful format for the decisionmaker.

**Goals and Standards -- Marrying Efficiency and Equity:** CBA can be given appropriate standing and introduced systematically into goal setting without compromising other social concerns by first developing regulatory goals or aspirations, ideally expressed as ranges of acceptable risk, based on health or other criteria that reflect equity or fairness concerns. Then CBA, defined broadly, would be used to justify where the standard would be set within this range or, to the extent that the range expressed aspirations versus more concrete requirements, how far toward the stated goal the regulation should go. An example of this approach can be seen in the Senate reauthorization of the Safe Drinking Water Act.

**Insuring Credibility of Analysis.** Agencies need to be clear about their justification for proceeding with a regulatory action, especially when the regulation fails an implicit or explicit cost-benefit test. They should have the scientific and economic assessments underlying major rules peer-reviewed, and both the analysis and peer review should be done early enough to influence the outcome, not as a rubber stamp to decisions made on other grounds. Peer review can be inside the agency (although EPA has recently dismantled this function), part of an interagency process, part of an expanded role for OMB, or even be privatized. The combination of expanded peer review and timely completion of analysis would also greatly support and enhance the performance and perceived credibility of the existing Executive Branch regulatory review process managed by OMB.

# An Assessment of the Risk Assessment Paradigm for Ecological Risk Assessment

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**Summary**

This document reviews the strengths and limitations of the paradigm for ecological risk assessment and its implementation. The review is derived from discussions with government and professional organizations, recent literature, and attendance at various relevant symposia, workshops, and other meetings. The prevailing paradigm for ecological risk assessment is reflected in the U.S. Environmental Protection Agency's (1992) *Framework for Ecological Risk Assessment* (Figure 1). The National Research Council (1993) published a similar paradigm.

The USEPA (1992) paradigm for ecological risk assessment expands upon the NRC's (1983) four-step paradigm presented in *Risk Assessment in the Federal Government: Managing the Process.* One of the earliest adaptations of the 1983 paradigm for use in ecological risk assessment is presented in Barnthouse and Suter (1986) and their work provided a starting point for the development of the *Framework*. Consisting of Problem Formulation, Analysis, and Risk Characterization components, the *Framework* illustrates the importance of communication between risk assessors and risk managers and the role of monitoring and other data collection efforts.

Strengths

Perhaps the *Framework's* greatest strength is that it is sufficiently flexible to apply to a broad range of environmental problems. In particular, the *Framework* attempts to broaden the conceptual approach beyond a perceived narrow view of risk assessment as the evaluation of a chemical's effect on a few species. The *Framework* has gained wide acceptance as the basis for developing ecological risk assessment methods and organizing risk assessments within many federal and state agencies. Most people surveyed by us found that the *Framework* provided an acceptable conceptual structure for developing more detailed guidance or for organizing ecological risk assessments.

An important characteristic and potential strength of the *Framework* is its introduction of the term "Problem Formulation" in place of "Hazard Identification" to characterize the nature of initial activities that should occur as part of the risk assessment process. Problem Formulation is the most critical step in ecological risk assessment because it provides direction for the analysis and should take into account the ecological, societal, and political issues related to the questions being addressed. Ecological problems can range from simpler analyses involving a single chemical and a limited number of species to more complex issues such as watershed-level assessments of multiple physical, chemical, or biological stressors. Ecological stressors may include an overabundance of essential nutrients (e.g., nitrogen loading), chemical contaminants, physical alterations (e.g., temperature, water levels, soil type), radionuclides, habitat loss or modification, oxygen consuming substances, introduced species, and genetically-engineered organisms. Ecological receptors affected by one or more of these stressors could include individual organisms, species, communities, habitats, and ecosystems.

The diversity of potential stressors and receptors indicates the care that must be taken at the Problem Formulation stage and its importance for structuring the assessment.

The Problem Formulation stage is also important because it attempts to integrate the perspectives of stakeholders, risk managers, and risk assessors. People do not have a common value system or knowledge base with respect to ecological or environmental issues. Communication among stakeholders, risk managers, and risk assessors at the Problem Formulation stage - as well as during the assessment - is, therefore, important for formulating the questions, identifying differences in perspective, and resolving issues.

The development of the *Framework* and the discussions related to its implementation have fostered the use of a common language for discussing the ecological risk assessment process. In addition, the *Framework* has helped define what is meant by an ecological risk assessment. This has been especially useful inasmuch as a diversity of terms and approaches have arisen to serve various environmental programs.

Limitations

The major limitations related to the paradigm regard knowing how and when to use it. The USEPA, other federal agencies, states, industry, and professional organizations are currently grappling with the development of guidance or approaches for conducting assessments. Much of the discussion in forums related to guidance development centers on fundamental components of the analyses, indicating that we are still at a basic level in understanding how to conduct ecological risk assessment. Further, while there is a growing recognition that the ecological risk assessment process should include ongoing communication among stakeholders, risk managers, and risk assessors, there is little guidance on how this should occur. The importance of communication with stakeholders is not identified within the prevailing *Framework* paradigm.

Risk assessments are tools and as such are better suited for some environmental problems than others. In most cases, risk assessments are used to help answer questions related to decisions. The choice to use risk assessment to answer the questions or help with the decisions will depend on the ecological issues and on other factors that may affect the decision. In this same vein, the complexity of the risk assessment should be appropriate to the question or decision and the level of uncertainty that can be accepted. To this end, a number of groups have identified the need for tiered or phased approaches for conducting assessments leading from simpler to more complex analysis. Finally, there may be cases where risk assessment or any other technical assessment can not meet expectations within an acceptable level of uncertainty due to limits in our understanding of environmental processes and predictive abilities. In such cases, risk assessment may still have value in identifying the extent of uncertainty and gaps in knowledge. However, it would be inappropriate to think that risk assessment has provided a clear "answer".

Recommendations

This review makes the following recommendations:

1. The USEPA's *Framework* should be accepted as the paradigm for most ecological risk assessments. However, the *Framework* could be augmented to: a) reflect the importance of communication among stakeholders, risk managers, and risk assessors throughout the process, and b) identify the iterative nature of risk assessments. The report presents a modified framework to address these issues (Figure 10).

2. Guidance should be developed for implementing components of the *Framework* through a series of case studies. This should be undertaken as a collaborative effort involving stakeholders, risk managers, and risk assessors. Guidance is especially needed in the following areas:

   *Problem Formulation*: This critical step establishes the direction and scope of the ecological risk assessment. The process by which this is done involves identifying the actual environmental value(s) to be protected (Assessment Endpoints) and selecting ways in which these can be measured and evaluated (Measurement Endpoints). The selection and articulation of Assessment Endpoints is the key starting place for the assessment. However, there is very little guidance on how this process should occur and who should be involved. Because of the fundamental importance of this step to the overall assessment, this process should be given the highest priority for guidance development. The selection and articulation of Assessment Endpoints is a focus of communication between stakeholders, managers, and assessors, and, therefore, guidance should be developed through a process that involves representatives from all of these groups.

   *Weight-of-Evidence Approach*: Many ecological risk assessments involve the conduct of a "weight-of-evidence approach". However, there is no consensus on the definition of weight-of-evidence" or how such an approach should be applied. Often the approach reflects an individual's professional judgement and the conclusions reached may not be transparent to others. A definition should be established for use in ecological risk assessment. Further, an effort should be undertaken to examine the professional judgements that underpin weight-of-evidence approaches and how they can be made more explicit. Finally, guidance for conducting quantitative and qualitative weight-of-evidence approaches should be developed. The 1995 report prepared by the Massachusetts Weight-of-Evidence Workgroup (contact Nancy Bettinger at Massachusetts Department of Environmental Protection) is an effort to address this need.

   *Tiered or Phased Approaches:* There is general agreement that risk assessments are best conducted using tiered or phased approaches. There is a need to establish how these should be structured and linked to management decisions. Because tiered assessments

are imbedded within management strategies, guidance development should include both risk assessors and risk managers. Related to the implementation of a tiered strategy is addressing the uncertainties inherent in the various levels of analyses. There are many sources of uncertainty in ecological risk assessment. These should be presented and discussed as part of the assessment. Methods for quantifying these uncertainties should be identified and evaluated. The uncertainty in the analysis should be addressed in a manner appropriate for the parties involved in the decision. For example, one goal of uncertainty analysis could be to insure that the decision is "protective" within a reasonable level of uncertainty.

*Risk Characterization:* Many of the groups surveyed by us identified this component as an area where guidance was needed. Available methods are considered to be limited and often overly simplistic. In some cases, risk characterization is interpreted simply as a restatement of test results. Risk characterization can be viewed as the final stage of a weight-of-evidence approach that relates the analysis results to the Assessment Endpoints. In screening level assessments, simple methods might be employed if these are adequate to answer questions with an acceptable level of protection. In more complex situations, it may be necessary to employ more sophisticated risk characterization tools. Guidance is needed both on when to use tools of varying complexity as well as which tools are most appropriate for a given problem. Ultimately the risk characterization should synthesize and provide information that can be understood and applied to risk management decisions. Identifying and characterizing the uncertainties in the analyses are important aspects of characterizing risks. These are often overlooked or excluded. Guidance is needed on how best to characterize and discuss uncertainty as part of risk characterization.

*Communication:* Ecological issues can pose communication difficulties among stakeholders, risk managers, and risk assessors. These individuals do not share common language systems and may not share common value systems. These differences are often not recognized and this can lead to problems throughout the assessment process. A better understanding of these differences is needed in order to learn how the groups can communicate more effectively. Discussions concerning the development of Assessment Endpoints is a useful place for exploring the nature of these differences and identifying methods for bridging gaps in understanding among the groups. This could be accomplished by working through a number of case studies.

3. Stakeholders should have greater involvement in the ecological risk assessment process. However, guidance is needed on how and when to involve stakeholders. For example, there may be many small or well-defined assessments that are part of established regulatory programs where it may not be practical to involve stakeholders in each and every case. Stakeholder involvement should be considered when generic guidance and guidelines are being developed for broad application. Stakeholder involvement should also be considered for larger local or regional assessments where the interests of stakeholders could be affected by the decision(s). The need for stakeholder involvement

at early stages within an ecological risk assessment is more important than for human health risk assessment because of greater diversity of values the public places on natural resources. Ultimately, it is the risk manager's responsibility to determine how to consider and incorporate the interests of stakeholders. This too is an area where guidance is needed.

4. Scientists, policy makers, and the public should be educated on the ecological risk assessment process, its strengths and limitations, and how and when it can be used as a tool to help answer questions or make decisions.

# Review of Noncancer Risk Assessment: Applications of Benchmark Dose Methodologies

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Abstract

The overall goal of this project is to evaluate risk-assessment methods traditionally used for noncancer health risks and to compare these methods with newly developed approaches. The report gives a brief economic rationale for preventing noncancer health effects, using figures for years of potential life lost, which reveal that noncancer health effects, such as birth defects, are of the same national economic magnitude as cancer and heart disease. Traditional methods for assessing noncancer risks include identification of no-observed-adverse-effect levels (NOAELs). Reference doses (RfDs) and acceptable daily intakes (ADIs) are derived by dividing NOAELs by uncertainty or modifying factors. Those factors represent a default approach to account for animal-to-human and average-to-sensitive population extrapolation or extrapolation from inadequately designed experiments. If all doses tested produce a response a lowest-observed-adverse-effect level (LOAEL) is used and a safety factor of 10 is applied. Those traditional approaches are compared with benchmark-dose methods in which a curve-fitting procedure is used to find a dose that produces a specific effect. Confidence limits are generated around that dose, which is set at the lower confidence limit to produce a specified percentage change in response. The benchmark dose (BMD) is used to calculate a reference dose.

The method is used for noncancer end points. Although the majority of applications of the BMD approach are related to developmental toxicity, it has also been applied to reproductive toxicity, neurotoxicity, and cancer. The method has been most thoroughly evaluated with reference to developmental toxicity in a series of 4 papers and technical documents by Faustman, Allen, Kavlock, and Kimmel that analyzed over 1825 experimental end points. The BMD method offers an alternative to traditional NOAEL approaches and is in general no more conservative than the use of NOAELs and includes a confidence-limit calculation. A log-logistic model for developmental toxicity has several advantages, and BMD values based on a safety factor of 5 with this model are similar to both continuous and quantal NOAEL values (without confidence limits). Traditional safety-factor approaches used for RfD calculation based on LOAEL values are over-conservative; a factor of 5 is more appropriate than a factor of 10. NOAEL values are not “riskfree” but represent effect levels ranging from below 5% up to 20% effect. That illustrates an important advantage of BMD approaches: a regulatory limit can be consistently set at a given response level rather than being dictated by study design. The BMD method rewards adequately designed experiments by setting higher BMDs, which is in direct contrast to the NOAEL approach. With curve-fitting procedures, the calculation of RfDs is no longer constrained to be one of the experimental doses tested. BMD methods will allow for easy transition to truly biologically based dose-response models when such models are developed.

# Comparative Risk Analysis for Priority Setting

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Abstract

Risk-based priority-setting has been accepted by many as the preferred strategy for deciding how to deal with resource-allocation issues. Supreme Court Justice Stephen Breyer, in a book before his appointment, analyzed the cost per death averted for various regulations and concluded that "the entire nation could buy more protection by refocussing regulatory efforts." The Carnegie Commission on Science, Technology, and Government encouraged greater use of comparative risk assessment (CRA). The National Academy of Public Administration, in reviewing Environmental Protection Agency (EPA) practices, suggested that risk-based priority-setting should be increased. Congress has mandated that comparative risk be used in determining which problems to address first.

CRA has evolved, and so has its definition. EPA defines it in a Guidebook to Comparing Risk and Setting Environmental Priorities ( September 1993) as both an analytical process and a set of methods used to systematically measure, compare, and rank environmental problems. It provides a common basis for evaluating net benefits and costs of different strategies for reducing or preventing ... risks ... Rankings can provide an important input to the priority-setting and budget processes when possible risk reduction and prevention strategies are considered in the context of other relevant non-risk concerns, such as economic viability, technological feasibility, and social equity.

CRA projects at the state level have involved hundreds of people from the public and private sectors. Typically, CRA projects at the state level have been carried out by several committees working in concert. These usually include a management committee (often from state or local government), a technical work group (scientists and researchers from the academic and activist communities and potentially industry), and a public advisory committee (representing interest groups). CRA is based on the analytic principles and approaches of rational public-policy analysis dating from the early 1970s. However, CRA has not been neatly, firmly, and finally established. The strength of the comparative-risk process is its ability to "frame" public-policy questions consistently and to engage people productively in addressing them. Its weakness is that the answers can be uncertain, unwelcome, or both. The ultimate goal for government officials, the CRA community, and the public, in using CRA as a tool for environmental planning and protection, is to synthesize the power of the scientific method with the insight of democratic participation.

There is still a high level of experimentation with the process. Indeed, too much standardization at this point could lead to the application of poorer methods. Also, CRA and goal-setting have not been institutionalized in federal or state agencies.

**Recommendations**

The following actions are recommended:

- Implement CRA for priority-setting in stages so that it does not overwhelm the human and technical resources.

- Keep CRA process flexible so that innovations can occur and priorities are not distorted by flawed rankings.

- Encourage innovation in CRA at the federal, state, and local levels and allocate resources for evaluation of process and outcome.

- Provide resources to train competent professionals to perform CRA.

**Legislative**

The role of comparative and traditional risk assessment, cost-benefit-analysis, and risk communication in shaping priorities has been the focus of congressional debate. These tools can provide insight into the effectiveness of regulatory and nonregulatory approaches to health and environmental protection, but they do not yield prescriptive guidance for decision-makers and can be resource-intensive and contentious among stakeholders. Resources must be provided to train professionals in these activities and to allow government, scientific, and public organizations to adequately carry out the analytic and stakeholder participation processes.

Legislation should set high thresholds for requiring complex analyses; doing a good job on a few assessments is important as the agencies build capacity to do more. It should also recognize the role of expert opinion and should give the risk manager discretion. The comparisons and tradeoffs are complex, and the uncertainty is often high. Allowing discretion and providing active oversight can be more effective than prescriptive guidance.

**Federal Executive Branch**

The Office of Science and Technology Policy and the Office of Management and Budget can identify opportunities for collaboration among agencies and encourage the development and transfer of expertise across the executive agencies. The main thrust must be at the agency level, where cross-program activities and multiagency involvement need to be encouraged. Problem-oriented temporary task groups from various agencies should be formed to coordinate on specific issues. The EPA-FDA task group on the effects of pesticide residues on children is a good example.

The interagency Task Force on Environmental Heart and Lung Disease and Cancer had a productive working group on risk communication that developed many effective workshops and publications. It provided a mechanism for interagency funding of projects of common interest and could be a model for interaction on risk-assessment issues.

**Support of Future State and Local Efforts**

Flexibility is crucial. EPA has adopted more flexibility in negotiating specific objectives with each state. Block grants have been proposed for other federal-state activities and are not new (health programs were funded through block grants in the 1970s). Block grants provide

flexible funding and cut administrative costs. However, there is a need to guard against consumption of money by routine activities at the expense of innovation.

In South Carolina in the 1970s the development of preventive public-health programs for chronic diseases would not have been possible without special funding outside the block-grant program. Special funding was provided through grants and cooperative agreements with NIH and CDC. With the special funding came a great deal of interaction with other states and experts from the science community. The CDC programs actually assigned a public-health advisor to the state. Technical support was also provided by such programs as the National High Blood Pressure Education program.

Those research and demonstration funds provided funding to define the problems and evaluate the effectiveness of intervention strategies. The efforts encouraged state funding for services and provided an effective means for building capacity at the state level.

# Communicating to the Public:
# Using Risk Comparisons

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Abstract

Ever since risk assessment has been used in the federal government to support decision-making, there has been a recognition that government agencies had no choice but to communicate with stakeholders, including the public. In 1987, William Ruckelshaus, former EPA Administrator, noted that the question is not whether to involve the public in decisions about risk, but how. In 1989, the National Research Council produced a report on risk communication and offered the following definition:

> Risk communication is an interactive process of exchange of information and opinions among individuals, groups, and institutions. It involves multiple messages about the nature of risk and other messages not strictly about risk that express concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management.

The risk communication process must address the following questions: Who will make the decision? How will technical estimates of risk and other factors be evaluated? How, when, and where will stakeholders' concerns be managed? What information do the stakeholders want or need?

Several characteristics of risk comparison and communication should be considered when evaluating the effectiveness of approaches for the study and practice of risk communication. Risk comparison can be a simple one-dimensional comparison or a more complex multidimensional comparison. At the simple end, similar risks and only a few aspects of each are compared. At the complex end, multiple risks are compared across a variety of dimensions. The simpler the comparison, the easier it is to communicate and produce a more predictable response. However, a simple comparison might not represent the situation accurately. If the risk comparison is more complex, it can yield richer perspective for the decision-maker and public, but might also be an attempt to relate risks that are so dissimilar that, to some target audiences, comparison does not seem relevant.

Several approaches, both theoretical and empirical, have been used to understand how target audiences respond to risk messages and to improve the quality of communication. Psychometric models have examined the effect of qualitative risk characteristics, such as whether a risk is new or familiar, in explaining how groups respond to risk messages. Other models are more econometric; they are based on contingent evaluation of perceived threats and perceived benefits. The latter seem more explanatory, but the amount of comparative research is very limited.

The mental-models approach seeks to understand how people use information to make decisions by using a structured-interview technique to identify knowledge, beliefs, missing information, and misconceptions. Providing information in a manner that conforms to the audience's "mental model" improves comprehension. Providing missing information and correcting misconceptions make decisions more consistent between lay and expert groups.

Because our theoretical understanding of risk communication is not full, a practical empirical approach is most effective. Focus-group and survey research suggests that a variety of qualitative characteristics of risk can influence the response to risk comparisons and that risk comparisons can exacerbate or trivialize concerns. Therefore, formative research, including message testing, should be a part of any risk-communication activity.

The research on risk communication provides insights into the utility of risk comparisons. They can be useful but only when they are a part of an overall communication strategy. This strategy requires that the communicator: understand the nature of the risk—both the hazard that it presents and the qualitative attributes that influence perception by the target audience; understand the audiences that are being addressed and their relationship to the hazard; understand how the risk comparison interacts with other components of the message; and have a way to evaluate the audiences' response.

Experience from risk communication suggests that risk comparisons should be made in ways that provide cues to action and that respect the values of the participants in the process. Failure to consider social and political issues and values will diminish the quality of the discussion. That does not mean that the scientific components should be de-emphasized in deference to values, but the technical components and their implications for risk management must be effectively and persuasively conveyed to all stakeholders, including the public.

Most research has been descriptive rather than experimental. It has been focused on specific risks, such as radon and toxic substances, rather than taking a more comprehensive view of environmental risks. The kind of community-based research in the 1960s and 1970s that has underpinned the prevention movement in health care has not been done for the environment. Some of our pressing environmental problems are more amenable to a broad public-health approach than to the traditional command-and-control regulatory approach.

The complex nature of risk communication calls into question the value of requiring simple comparisons of risk end points with either common risks of daily life or other chemical or physical risks. Without a context, this information might yield wrong or confusing messages for the public. For most listeners, it evades the primary questions, "Will it hurt me?" Therefore, risk-communication efforts should provide both comparisons and context, which can depend on factors beyond risk numbers.

**Recommendations for Practice**

Include communication as a specific component of all risk-management plans and budgets (10% of available resources is a good rule of thumb).

Hold risk-program managers accountable for meeting communication objectives.

Use appropriate formative research to underpin communication efforts.

Communicate uncertainty with care. Because stakeholders, including the public, might

react to uncertainty in unpredictable ways, ensure that a good mechanism to evaluate what has been communicated is in place.

Use effective communication strategies to build and extend the consensus among stakeholders, including the public. Clear consensus-building (e.g., with comparative risk assessments) can provide support for using more persuasive communication techniques.

**Recommendations for Research**

Conduct experimental studies on the influence of risk comparisons on attitudes and behavior of stakeholders, including the public.

Fund innovative demonstration efforts at the national, state, and local levels.

Conduct research on the effectiveness of various techniques for presenting uncertainties in environmental risk assessment.

Conduct research on strategies that make regulatory standards flexible.

# Appendix A.6

# Federal Agency Risk Assessment and Risk Management Practices

# Federal Agency Risk-Assessment and Risk-Management Practices[1]

## Introduction

According to its charter, the Commission is charged with investigating "the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws." Current practices in these areas vary among Federal agencies and even among regulatory programs within the EPA. Some of this variation is attributable to different requirements among the Federal laws authorizing regulatory activity, either in the form of explicit methodologic requirements that assessments must follow or as differently mandated regulatory responsibilities that the assessments must support. Other differences reflect variations in policy among organizations, adopted as a matter of differing scientific and policy judgment or simply because of the independent establishment of varying precedents and preferences.

This array of methods reflects the fact that there is no single, agreed upon scientific procedure for the assessment of health risks from chemical exposures. The primary reason is that the needs of the risk assessment process, to make projections of possible human health risks for the variety of types and levels of exposures that may arise, far outstrip the ability of scientific investigation to give firm answers. The practical need remains, however, to make characterizations of the risk consequences (including the uncertainty about those consequences) of various potential actions and activities by industries, by government, by individuals, and by society as a whole.

Faced with this practical problem, regulatory agencies have arrived at practical methods. These methods include reliance on procedures that, while attempting to embody information from the available data, of necessity rely on uncertainty-bridging principles derived from a combination of general knowledge about chemicals, their behaviors in the environment and their toxic effects, a desire to maintain internal case-by-case consistency in how uncertainties are resolved, and a desire to ensure that regulatory decisions are likely to fulfill the legislative mandates about public health protection.

The basic issues of chemical health risk assessment and the role of risk assessment methods, default assumptions, and conservatism have been discussed in the National Academy of Sciences Report, *Science and Judgment in Risk Assessment* (NRC, 1994). This document builds on earlier works taking a comprehensive view of risk assessment and the principles underlying its conduct, especially *Risk Assessment in the Federal Government: Managing the*

[1]This appendix was prepared using material taken from a report prepared for the Commission by Dr. Lorenz Rhomberg of the Center for Risk Analysis at the Harvard School of Public Health.

*Process* (NRC, 1993), widely known as the "NAS Red Book," and *Chemical Carcinogens: A Review of the Science and Its Associated Principles* [50 FR 10371-10442], widely known as the "OSTP Principles."

These documents epitomize an ongoing discussion that has largely succeeded in defining a common framework and structure for risk assessment. Within this framework, however, there continues to be vigorous debate about the most appropriate risk assessment approaches, the bearing of various kinds of data on risk projections, and the degree and appropriateness of conservatism in risk assessment methods. Faced with this continuing disagreement about methods, various Federal regulatory agencies have adopted somewhat different procedures. In part, this diversity can be attributed to the different questions being asked of the risk assessment process in different regulatory contexts by different environmental statutes. In part, it reflects different institutional judgments about the most appropriate methods and different scientific judgments about matters with high scientific uncertainty. And in part, it reflects simple policy choices made for the sake of consistency within each organization (which, owing to independent histories, becomes inconsistent among organizations).

The effect of this diversity of methods among Federal regulatory agencies is to make it difficult to compare risks, or the actions taken to mitigate those risks, from one regulatory program to another. One program's concern for a one-in-a-million cancer risk, say, may be based on an upper bound low-dose extrapolation to an average person in the exposed population extrapolated from mice based on a presumption of equal toxicity when daily doses are scaled by surface area, while another program's one-in-a-million is for a hypothetical person exposed to an agent at the regulatory limit for 45 years based on a maximum likelihood low-dose extrapolation and the presumption that equitoxic doses are proportional to body weight.

Although defaults and standard methods are necessary in the face of uncertainty and lack of case-specific knowledge, variation from group to group in these defaults enhances the sense of arbitrariness in risk analyses. In cases where regulatory responsibilities overlap or when different groups have cause to assess the same exposures, differences in assessment outcome can lead to conflict and confusion among the public and the regulated community.

This chapter attempts to sort out some of those sources of confusion by analyzing the public health mandates and regulatory powers of a number of risk-related regulatory programs' enabling statutes (see Table A.6.1), along with risk assessment and risk management practices as they have evolved in response to those statutes. Special attention is focussed on the laws' requirements about who in the exposed population is to be protected, and how sufficiently protective standards are defined. A summary overview of Federal risk-based regulations, mandates, statutory language, and principal differences in risk assessment methods is provided in Table A.6.2.

**Table A.6.1. Environmental regulatory statutes addressed in this report.**

| Abbreviation/ Citation | Statute Title | Responsible Federal Office |
|---|---|---|
| **CAA**<br>42 U.S.C.A. §§ 7401 to 7671q | Clean Air Act | EPA, Office of Air and Radiation (OAR) |
| **CWA**<br>33 U.S.C.A. §§1251 to 1387 | Clean Water Act (Federal Water Pollution Control Act) | EPA, Office of Water (OW) |
| **SDWA**<br>42 U.S.C.A. §§300f to 300j-26 | Safe Drinking Water Act (Public Health Service Act) | EPA, Office of Water (OW) |
| **RCRA**<br>42 U.S.C.A. §§ 6910 to 6992k | Resource Conservation and Recovery Act (amending Solid Waste Disposal Act) | EPA, Office of Solid Waste and Emergency Response (OSWER), Office of Solid Waste (OSW) |
| **CERCLA**<br>42 U.S.C.A. §§ 9601 to 9675 | Comprehensive Environmental Response, Compensation, and Liability Act | EPA, Office of Solid Waste and Emergency Response (OSWER), Office of Emercency and Remedial Response (OERR) ["Superfund"] |
| **TSCA**<br>15 U.S.C.A. §§2601 to 2692 | Toxic Substances Control Act | EPA, Office of Prevention, Pesticides, and Toxic Substances (OPPTS), Office of Pollution Prevention and Toxics (OPPT) |
| **FIFRA**<br>7 U.S.C.A. §§ 136 to 136y | Federal Insecticide, Fungicide, and Rodenticide Act | EPA, Office of Prevention, Pesticides, and Toxic Substances (OPPTS), Office of Pesticide Programs (OPP) |
| **FFDCA**<br>21 U.S.C. §§ 321 to 394 | Federal Food, Drug, and Cosmetic Act | Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN); *and* EPA, Office of Pesticide Programs |
| **OSHAct**<br>29 U.S.C.A. §§ 650 to 683 | Occupational Safety and Health Act | Department of Labor (DOL), Occupational Safety and Health Administration (OSHA) |
| **CPSA**<br>15 U.S.C. §§ 2051n to 2084 | Consumer Product Safety Act | Consumer Product Safety Commission (CPSC) |
| **FHSA**<br>15 U.S.C. §§ 1260 to 1278 | Federal Health and Safety Act | Consumer Product Safety Commission (CPSC) |
| **APA**<br>5 U.S.C.A. §§ 551 to 559 | Administrative Procedures Act | |

**Table A.6.2 Summary overview of Federal regulation of potentially toxic chemicals, including risk mandates, key statutory language, and principal differences in risk assessment methods among Federal regulatory programs.**

| Program Office | Statute/ Activity | Risk Mandate | Role of Carc Class. | Special Quant Methods | Individual Risks Considered | Population Risk Considered | Special Groups | Usual Acceptable Residual Risk | Practical Regul. Trigger or Criterion |
|---|---|---|---|---|---|---|---|---|---|
| OPPTS-OPPT "Toxics" | TSCA | avoid and mitigate "unreasonable risk" via risk-benefit balancing | no | "additional" cancer risk above background | yes, "reasonable worst case" for occup expos | yes, indirectly | workers, consumers, genl popn | unstated, but usually $10^{-5}$ to $10^{-6}$ for non-occup-ational, $10^{-4}$ to $10^{-5}$ for occup | |
| OPPTS-OPP "Pesticides" | FIFRA (registr.; use limits) | balance risks, benefits, social & economic costs; efficacious yet w/o "unreasonable risk to man or environment" | no QRA for *some* "C's" | | yes, broadly, assume max permissible residues, but average food consumptions | yes | | unstated, but usually $10^{-5}$ to $10^{-6}$ for non-occup-ational, $10^{-4}$ to $10^{-5}$ for occup | interplay of efficacy and tolerances for residues; registrant proposes use limits |
| | FFDCA (residue tolerances) | "Delaney Clause," no additives that are animal carcin.; "reasonable certainty of no harm" for residues | any pos cancer assay triggers Delaney | | no for carcinogenic additives; yes for residue tolerances | yes for residue tolerances | demogr. sub-population diets considered | zero for additives; $10^{-6}$ for assumed max residues in average diet, $10^{-6}$ for non-dietary exposure | Delaney prohibition of carcinogenic additives |
| OW | SDWA (drinking water) | for carcinogens, unenforceable max contam limits (MCL) of zero, but enforceable goals (MCLG) set by technology if within adequate margin of safety | yes, "C's" may be treated as threshold | extra UF on NOAEL for "C's" | a standard exposure scenario in middle range | no | no | $10^{-4}$ to $10^{-6}$ is range considered to be adequate | MCLG's primarily based on technical, cost feasibility if risk range hit. |
| | CWA (waterway water qual) | protect public health and welfare with non-enforceable, health-based water quality criteria and enforceable "best" technology based effluent standards | no | conserv. water transport models determine acceptable daily loading of water bodies | a standard exposure scenario in middle range | no | no | $10^{-5}$ to $10^{-7}$ | standards set by states with EPA guidance; some consideration of residual risk after best avail tech effluent limits |

| Program Office | Statute/ Activity | Risk Mandate | Role of Carc Class. | Special Quant Methods | Individual Risks Considered | Population Risk Considered | Special Groups | Usual Acceptable Residual Risk | Practical Regul. Trigger or Criterion |
|---|---|---|---|---|---|---|---|---|---|
| OSWER | RCRA (haz waste handling, active disposal) | aim at "cradle-to-grave" stewardship; technology- and process-based, but also risk-triggered corrective action, to be protective of human health and the environment, excluding costs | in some haz waste ID criteria; C's may be treated specially | uses OW MCL's or its own QRA to list or delist as a haz waste | yes, a rather conservative estimate of hypothetical transport and exposure near a problem site, but uses some Monte Carlo modeling | no | hypothetical populations around haz waste facilities | listing: $10^{-5}$<br>corrective action: $10^{-4}$ to $10^{-6}$<br>incinerators: $10^{-5}$ | cleanup strategy chosen with site-use, feasibility considerations as long as within risk range of $10^{-4}$ to $10^{-6}$ |
| | CERCLA Superfund, abandoned and active haz waste site monitoring and cleanup | applicable other laws plus cleanup to be protective of human health and environment; risk-based but consider feasibility | no | consider cumulative risk of mixtures (but not exposure to multiple sites) | "reasonable maximum exposure" using mix of midrange and conservative assumptions | high population around site prompts listing on NPL | hypothetical populations around site, scenarios for special groups (real or hypothetical) | $10^{-4}$ to $10^{-6}$, depending partly on anticipated future use of site | site-specific "ranking" QRA for listing, prioritization of site; then more detailed risk assessment to choose actions reaching target risk range of $10^{-4}$ to $10^{-6}$ |
| OAR | CAA Criteria pollutants | adequate margin of safety to protect public health | non-cancer only | extensive data, including on humans | yes | yes | | | without harmful effects on most people |
| | CAA Hazardous Air Pollutants | Must apply Max Avail Control Technology;<br>If residual risk to MEI >$10^{-6}$, further regulate to provide adequate margin of safety to protect public health, considering costs | no | Maximally Exposed Individual for each source can trigger residual risk provision | Only after MACT; MEI >$10^{-6}$ triggers further action; MEI <$10^{-6}$ before controls yields de minimis exemption | presumably yes, when assessing residual risk | populations around sources | <$10^{-6}$ ?? | apply best controls as default, then consider further regulation if needed |

| Program Office | Statute/ Activity | Risk Mandate | Role of Carc Class. | Special Quant Methods | Individual Risks Considered | Population Risk Considered | Special Groups | Usual Acceptable Residual Risk | Practical Regul. Trigger or Criterion |
|---|---|---|---|---|---|---|---|---|---|
| FDA | FFDCA (food additives, colors & contam-inants; cosmetics ) | “Delaney Clause,” no additives that are animal carcin.; "reasonable certainty of no harm" for residues, no cost considerations | any pos cancer assay triggers Delaney | "modified" Gaylor-Kodell procedure for carcinogens, body weight dose scaling | no for carcinogenic additives; yes for additives, contaminants | no | demogr. sub-population diets considered | zero for additives; $10^{-6}$ for assumed max residues in "high use" diet | Delaney prohibition of carcinogenic additives |
| OSHA | OSHAct (occup. exposures) | "no employee will suffer material impairment of health," considering feasibility of stds | no, frequent use of human data | MLE of multistage model, body weight dose scaling | yes, for full working life at permissible exposure limit | no | no | feasible controls | "significant" risk (in practice, $10^{-3}$) |
| CPSC | CPSA FHSA (consumer products) | "to protect...against unreasonable risk of injury" with "reasonably necessary" standards, considering cost/benefit | scheme similar to EPA's, focus on agents with "sufficient evidence" | MLE if linear, surface area dose scaling, combine tumor types | not explicitly | yes, in context of cost-benefit analysis | impact of regulation (not risk) on elderly, handicapped | unclear | "reasonably necessary," least burdensome standards with benefits "bearing a reasonable relationship" to costs |

## Survey of Practices

### Food and Drug Administration

The Food and Drug Administration (FDA), which resides within the Department of Health and Human Services, has a number of divisions. The primary one of interest to this report is the Center for Food Safety and Applied Nutrition (CFSAN); most of the FDA's assessment of potential human health risks from exposure to chemical substances is conducted by CFSAN in conjunction with its regulatory responsibility over additives and contaminants of foods and cosmetics.

The principal legislation on which FDA's authority is based is the Federal Food, Drug, and Cosmetic Act (FFDCA). Although it has been much amended over the years, the original act dates to 1906, making it by far the oldest among federal laws concerned with the regulation of public health risks from toxic substances. As such, much of the methodology for safety evaluation and risk assessment had its origin and early evolution in the implementation of parts of the FFDCA. The act had its origin in response to widespread scandals and "muckraking" exposés of poisonings from dangerous patent medicines, unwholesome meat packing, adulterated foods, and misrepresentations in labeling. Accordingly, the provisions of the act stress avoidance of "filthy, putrid, or decomposed" ingredients, sanitary conditions for processing and packing, proper identification and labeling, and strict limits to prevent "adulteration" of foodstuffs. It is in these adulteration provisions that toxicological risk assessment issues arise—foods are considered adulterated under the act when they contain "added substances" that are poisonous or injurious to health. The application of the act becomes somewhat arcane because the law distinguishes several categories of added substances: food additives, color additives, pesticides, and animal drugs. The question of pesticides is further complicated by the fact that regulatory authority over pesticides is shared by FDA under the FFDCA and the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

"Food additives" (regulated under §409) exclude adequately tested substances listed by the agency to be recognized as safe "among experts qualified by scientific training and experience to evaluate its safety" (§201); otherwise, the safety of additives is established by the agency's granting of a petition by the would-be user (although agency initiative is also allowed and pursued in practice). The petition must contain experimental and toxicological data bearing on the evaluation together with a statement of the conditions of proposed use. In its response, the agency specifies conditions of permissible use (which may differ from those proposed) and maximal concentrations that may remain in the food when marketed. Section 409 specifies that, in considering what uses are safe, "the Secretary shall consider among other relevant factors...the probable consumption of the additive,...the cumulative effect of such additive in the diet..., taking into account pharmacologically related substances,...[and] safety factors which in the opinion of experts qualified by scientific training and experience...are generally recognized as appropriate for the use of animal experimentation data." (Although this is phrased quite generally, this still ranks as one of the more specific statements about risk

assessment methods to be found among environmental laws.) Section 409 also stipulates that tolerances should be set no higher than is "reasonably required to accomplish the physical and other technical effect for which such additive is intended" notwithstanding the fact that higher levels might be deemed safe. "Color additives" are regulated under a separate section of the act (§721); other than some procedural differences, however, the risk assessment provisions are similar to those applying to additives.

This methodologic prescription applies only to non-cancer toxic effects, however, because at §409(c)(3)(A) the FFDCA contains a very specific statement about how the safety of potentially carcinogenic food additives is to be treated. This is the well known "Delaney Clause," named after the sponsor of the 1958 amendment under which the provision was included in the act. It states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." The rationale cited at the time of the Delaney Clause's adoption was that carcinogens may be without a threshold concentration of toxic action; thus no exposure level could be declared "safe." This stipulation prohibits consideration of the quantitative level of risk that an additive might pose, effectively avoiding the quandary faced under other environmental laws of defining "acceptable" levels of cancer risk.

The Delaney Clause specifically exempts "the use of a substance as an ingredient of feed for animals which are raised for food production" if it is found that "no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary...) in any edible portion of such animal after slaughter...or in any food...derived from the living animal" [§409(c)(3)(A)]. This so-called "DES proviso" was added (in 1962) to allow the use of potentially carcinogenic animal drugs (such as diethylstilbestrol, or DES) as long as they did not harm the treated animals and left "no" residues in the derived food products. The weakness of this formulation became evident as methods for detection of chemical residues became more and more able to detect tiny, even infinitesimal amounts. This led to a quandary: the Secretary could fail to specify the most sensitive existing methods (thereby technically avoiding "detection" of chemicals known scientifically to be present) or he could specify that technical advances in detection should be used (thereby indirectly reversing decisions about "safety" of additives even though knowledge about their safety was not what was changing). Debate about the Sensitivity of Method standards produced the realization that the true issue was not about changing detectability, but about the potential for minute quantities of the agent to cause meaningful risk. This debate led to the development of the first methods for quantitative risk assessment of carcinogens at the FDA.

As with most environmental laws, the mandates in the FFDCA about risk are phrased generally and depend on interpretation. Section 409, applying to additives, requires that only uses that may be demonstrated to be "safe" be permitted. Soon after this section's addition to the FFDCA in 1958, the agency officially defined "safe" as meaning "that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use" but recognized that absolute safety could not be definitively

guaranteed (21 CFR 170.3). (This has commonly been codified into the phrase "a reasonable certainty of no harm," which is widely regarded as a quotation from §409, although it does not in fact appear in the act.) Under §409, consideration of benefits and costs is not allowed.

Section 408, applying to non-concentrating pesticide residues, requires setting tolerances "to the extent necessary to protect the public health," but also states that "appropriate consideration" be given "to the necessity for the production of an adequate, wholesome, and economical food supply." That is, costs and benefits are to be weighed, albeit in an unspecified way.

As with other environmental laws with generally phrased mandates about risk, the specifics of how risk assessment is conducted in practice at the FDA depends on the particular procedures put in place to implement the mandate. Remarkably little of this implementation is firmly documented in citable policy documents, guidelines, or standard operating procedures. This is particularly true of the FDA. Some ascribe this to a desire to maintain as much flexibility as possible in the face of the rigidity and draconian nature of decisions mandated under the Delaney Clause, but it is perhaps more reasonable to note that the history of risk assessment at FDA is long and represents a period of considerable evolution of the role of risk considerations in regulation, from qualitative, *ad hoc*, and peripheral to quantitative, codified, and central. Much of the methodology was invented in attempts to respond to new and emerging needs from the regulatory process. In any case, the methods are codified largely in the history of evolving practice at the agency and in the documentation of regulatory actions (e.g., in the preambles to rules, laying out methods of analysis, in *Federal Register* notices).

To a great extent, the FDA relies on seminal publications outlining risk assessment principles as the grounding for its methods. These include the Red Book and the OSTP Principles. These expert consensus documents largely reflect compilation of insights and approaches first developed at FDA along with their elaboration and further development by the agency and other risk-assessing institutions. Unlike the EPA, however, the FDA has no officially published "guidelines" that establish standard methods for conducting risk assessment.

**Occupational Safety and Health Administration**

OSHA was created by, and has its regulatory authority under, the Occupational Safety and Health Act of 1970. (Because the agency and the act share the same acronym, the act is typically abbreviated as "OSHAct" and the agency itself as "OSHA.") The act's stated purpose is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions" by several means, including "providing medical criteria which assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience" (OSHAct §2). It was passed during the heyday of public concern about environmental health that also saw the founding of the Environmental Protection Agency. Regulatory decision-making under the OSHAct is formally invested in the Secretary of Labor.

The act mandates in §5(a) that "Each employer...shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm." The regulatory authority of OSHA is provided by §6 of the act, which sets out methods and criteria for issuance of occupational safety and health standards. In particular, §6(b)(5) states that "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents...,shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard...for the period of his working life." This paragraph further states that "In addition to the attainment of the highest degree of health and safety protection for the employee," the Secretary must consider "the feasibility of the standard" and that "Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."

In other words, the achievement of safe and healthful workplaces is to be brought about by the setting of enforceable workplace standards, in practice framed primarily in terms of allowable limits to employee exposure. For a workplace to be considered healthful, the limits to exposure are to be set so that an employee could be exposed at the limit for an entire working life without suffering harm. The authority is over the exposure limits, not over how they are achieved. In practice, engineering controls are preferred to respirators, where feasible. In §6(b)(7), however, it is stated that "Where appropriate, such standards shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards." (This paragraph goes on to prescribe labels, warnings, and provisions for ongoing monitoring of employee exposure.)

The OSHAct does not mention risk assessment as such, nor does it say much about the establishment of safe exposures. It is more explicit than some other laws about what constitutes an adverse health effect, however. In §2 it refers to "diminished health, functional capacity, or life expectancy" while §6 mentions "material impairment of health or functional capacity" as outcomes to be avoided. The mandated focus is on individual risk to a hypothetical employee experiencing an agent at the permissible exposure limit for a working lifetime, with regulation set "to the extent feasible" so that such an employee will suffer no impairment. The interpretation of these provisions has undergone considerable evolution as the result of some key judicial challenges. A full account is beyond the scope of this report, but the history and issues are reviewed by Graham et al. (1988).

Initially, the mandate was interpreted as essentially a health-based standard with an added proviso that health-based regulations could not be set so low as to be infeasible, interpreted as meaning having significant financial impact on the industry. For carcinogens, the lack of demonstrable exposure thresholds for toxic effect was interpreted to mean that no workplace exposure standard, however low, could assure that "no employee will suffer material impairment of health." Accordingly, the "feasibility" provision becomes the limiting factor, and workplace standards for carcinogens were set as low as was deemed to be technically feasible at reasonable cost. Under this interpretation, in a proposed "carcinogen policy" (42

FR 54148, 1977), risk assessment for carcinogens played a rather minor role in OSHA's setting of workplace standards, and OSHA staff generally argued that the uncertainties of quantitative cancer risk assessment precluded its use as a basis for regulation.

A proposed 1 ppm standard for workplace benzene exposure set under this interpretation was challenged in court, eventually leading to a 5-4 Supreme Court decision [Industrial Union Department v. American Petroleum Institute, 448 U.S. 607 (1980)], commonly known as the "benzene decision," which imposed fundamental changes in the interpretation of the OSHAct mandate. The court ruled that, before issuing a standard, OSHA must first demonstrate that the chemical posed a "significant risk." Unless the risk is significant, the material does not become a "toxic material" or "harmful physical agent" controllable under the act, and its presence cannot be said to meaningfully lead to an unhealthy workplace. A key part of this finding was that the §3(8) definition of a standard as a "reasonably necessary or appropriate" action was taken as grounds that action under §6(b)(5) must be shown to be necessary in some quantitative sense. While stating that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty," the court ruled that the case for significant risk could in principle be made using quantitative risk analysis. On the question of how large a cancer risk is "significant," Justice Stevens, in his opinion, stated that this was OSHA's responsibility, conceded to be a matter of policy, but that "If, for example, the odds are one in a billion..., the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand..., a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it."

In effect, the benzene decision prompts OSHA to conduct quantitative risk assessment in order to set standards for carcinogens. The court declined to address the related question about whether the "feasibility" and "reasonably required" standard-setting issues should be interpreted to require cost-benefit analysis of proposed standards. In a later supreme court decision, the "cotton dust decision" [American Textile Manufacturers Institute v. Donovan, 452 U.S. (1981)], the court ruled that OSHA may set a level as protective of health as feasible, even if a less stringent one has a more favorable cost-benefit ratio.

One further court case of note is the recent ruling [AFL-CIO v. OSHA, 965 F.2d. 962 (1992)] that OSHA must make its risk case for each chemical according to its own analysis. The practice of adopting outside standards, and of setting standards based on general risk arguments rather than case-by-case demonstration of significant risks, was struck down, invalidating 428 OSHA permissible exposure limits.

Since the benzene decision, risk assessment at OSHA has been dominated by the question of showing "significant" risk from exposure to workplace carcinogens. The question that Justice Stevens threw back to OSHA in his benzene opinion—what constitutes a "significant" risk (within the limits he set)?—has never been fully answered. Justice Stevens' statement that a lifetime risk of one in a thousand is clearly significant has served as something of a benchmark; in practice risks below $10^{-5}$ are rarely given much significance, but the lower bound on risks considered significant is hard to define because it is difficult to show. There is

no real case to date where OSHA did not pursue a standard because cancer risks were calculated to be low. In this case, the "significance" question is one of individual risk (rather than of public health impact on the whole exposed population), because the question is still posed in terms of the hypothetical worker exposed at the permitted limit. (OSHA has a policy of forbidding rotation of employees through jobs with high carcinogen exposure as a work practice to ensure no employee experiences a PEL for a 45 year working life. The grounds are that this strategy would only increase the number of workers exposed. In essence, this is a population risk argument.)

In practice, the technical and financial feasibility of achieving a standard is usually the limiting factor in choosing a permissible exposure level (P. Infante, personal communication). That is, limits are usually proposed under which a worker exposed to that limit would be calculated to experience risk in the upper end of Justice Stevens' range. (This is not to say that real workers with their actual exposures are necessarily suffering significant risk.) Under these conditions, the particular numerical estimate of risk level is not the driving issue in regulation, only the more general argument that "significant" risks could be generated. OSHA is able to entertain a variety of risk analyses based on somewhat different data sets and assumptions without muddying the regulatory decision with questions about which single analysis is the "right" one to choose to set a standard.

In the analyses that in practice drive the permissible levels specified in standards—that is, the determination of what levels are feasible to achieve—the costs and performances of various technical control options are considered. In these analyses, actual worker exposure levels and durations of exposure can be considered, including the resulting changes in residual risk to be expected after various regulatory options. Thus, there is opportunity, albeit indirect, for information on distributions of actual exposure to come into play in determining OSHA regulations. Nonetheless, the key consideration in feasibility is not risk, but rather the costs and technical ability needed to reach various ambient concentration levels.

Although the benzene decision has profoundly affected OSHA's approach to the analysis of risk, the practical result is that decisions are not very different from what would have been done under the pre-1980 carcinogen policy. The benzene decision stated that OSHA could not simply limit exposures according to feasibility of control without first showing that lack of control leads to significant risk. In practice, this is usually shown, at least for the standards that OSHA has pursued since 1980, so controls are set primarily on feasibility all the same. The role of risk assessment in this process is largely to establish (1) that significant risks exist under current exposures, and (2) that reducing the exposure as proposed in the standard will reduce the risk. The major practical impact is that the case for significant risk must be made for each compound, focusing the agency's activities and resources to pursue regulation on those compounds where risk can be clearly shown. Feasibility is a particular problem for OSHA because the characteristics of the indoor environment make it very difficult to control exposures to levels that other agencies might seek.

The principal notable features of risk assessment at OSHA are that the size of the risks in

question are a good deal larger than those encountered in other regulatory programs. Frequently, risks may be assessed on human data directly relevant to the regulatory interest; in recent years about one-half of OSHA PELs have been based primarily on human data. Even when animal data are used, human exposures of interest are often not far below the tested levels. Real, directly relevant exposure data are often available, and they are often quite defined and less variable compared to environmental exposures for the general population. As a consequence, OSHA risk assessments have to grapple much less with extrapolation questions, and OSHA's methods have less built-in conservatism (for example, use of maximum likelihood estimates instead of upper bounds). Since PELs are in practice set by feasibility, with risk assessment determining the need for controls, OSHA is able to entertain a variety of risk analyses without settling on a single "number" as the canonical one for its regulatory activities. The regulatory focus is on the risk to a worker exposed to the permitted level for a full working life; although in practice and for a variety of reasons, this hypothetical exposure may not be much higher than that actually experienced by many workers, and indeed some workers (those doing overtime or previously exposed under a higher standard, for example) may exceed this theoretical "maximum."

**Consumer Product Safety Commission**

The Consumer Product Safety Commission is an independent agency charged with regulatory responsibility over the safety of consumer products (which are defined by law to exclude foods, drugs and pesticides, regulated under FFDCA, as well as tobacco and certain other products regulated elsewhere). The commission was established by the Consumer Product Safety Act (CPSA) of 1972. The regulatory authority over hazardous substances in consumer products derives from the CPSA and the Federal Hazardous Substances Act (FHSA), which has existed since 1960. The FHSA was formerly administered by the Food and Drug Administration, but authority was transferred to the commission by §30(a) of the CPSA.

The CPSA establishes the Consumer Product Safety Commission with the mandate "to protect the public against unreasonable risks of injury associated with consumer products" and "to develop uniform safety standards" [§2(b)]. The agency is run by a five member commission appointed by the president (with the consent of the Senate) for seven-year terms. (In recent years, only three commissioners have been appointed, and in this circumstance, two constitute a quorum.) Decision-making by the commission is by majority vote among commissioners who may have been appointed by different administrations. This makes the development of analyses to support decisions somewhat different at CPSC than at agencies answering to a single administration appointee. Staff develop positions and options for the commission's consideration, laying information out for a final, publicly held, sometimes contentious debate.

The impetus is on the commission to promulgate consumer product safety standards when it is deemed necessary to protect the public against unreasonable risks of injury. That is, its task is to identify and act against hazards as opposed to endorsing products as "safe." Although much of the focus of the CPSA is on acute hazards, there are specially mentioned provisions for chronic toxicity, as discussed below. The commission has a wide variety of regulatory options

that can be applied as deemed necessary, including labeling, mandating other provision of information, endorsement of voluntary standards, manufacturing standards, product performance standards, bans, and recalls [CPSA §§7,8,15].

The FHSA defines a hazardous substance (or mixture) as one that is corrosive, an irritant, a strong sensitizer, or flammable, or one that "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children" [FHSA §2(f)(1)(A)]. Section 3 of this act gives authority to "declare by regulation any substance or mixture of substances which...meets the requirements" of this definition to be a hazardous substance. (Section 3 specifies a series of procedures which includes the right to petition for hearings; it is these more extensive procedural requirements, in addition to the focus on chemical hazards, that chiefly distinguishes regulation under the FHSA from that under the CPSA.) Labeling of substances declared to be hazardous is mandated. However, if "notwithstanding such cautionary labeling...the degree or nature of the hazard...is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance...out of the channels of interstate commerce," the substance can be declared a "banned hazardous substance" [§2(q)(1)].

Many of the provisions of the CPSA and the FHSA apply to both acute and chronic hazards. There is a particular provision in the CPSA regarding chronic hazards, however. Before any rule "relating to a risk of cancer, birth defects, or gene mutations" can be proposed, the commission must appointment a Chronic Hazard Advisory Panel of independent scientific experts [§28] from nominations by the president of the National Academy of Sciences; "the Commission shall request the Panel to review the scientific data and other relevant information...to determine if any substance in the product is a carcinogen, mutagen, or a teratogen." If so, "the Panel shall include in its report an estimate, if such an estimate is feasible, of the probable harm to human health that will result from exposure to the substance" [CPSA §31(b)].

In promulgating a rule, the commission must make findings regarding "the degree and nature of risk...; the need of the public for the consumer products subject to such rule, and the probable effect...upon the utility, cost, or availability of such products...; and...any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety" [CPSA §9(f)(1)]. The final regulatory analysis of the rule must contain "A description of the potential benefits and potential costs of the rule, including... [those] that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits and bear the costs" [§9(f)(2)]. Such analysis must also be included for "alternatives to the final rule which were considered, together with...a brief explanation of the reason why these alternatives were not chosen." The commission is prohibited from promulgating a rule unless it finds "that the rule...is reasonably necessary to eliminate or reduce an unreasonable risk of injury; that promulgation of the rule is in the public interest;...that the benefits expected from the rule bear a reasonable relationship to its costs;

and...that the rule imposes the least burdensome requirement which prevents or adequately reduces the risk of injury" [§9(3)]. It must also find that no currently implemented voluntary standard will suffice and that, if the rule is a ban, no other reasonable rule would protect the public. (As with most risk analyses, these findings are protected from judicial review unless the final rule itself is challenged.)

The requirements of the CPSA for rulemaking to include a statement on "the degree and nature of risk" [CPSA §9(f)(1)] and for each Chronic Hazard Advisory Panel to "include in its report an estimate, if such estimate is feasible, of the probable harm to human health" [§31(b)] constitute a fairly clear statutory call for the conduct of risk assessment. In addition, however, perhaps more than any other agency, the CPSC is explicitly required to justify its regulation in terms of costs and benefits. Whereas other cost-benefit balancing laws (e.g., FIFRA) merely make brief mention taking costs and feasibility into account, the consumer product laws lay out a series of specific findings that must be made.

The extensive need under the existing consumer protection statutes to cast regulatory risk analyses in terms of costs, benefits, impact on consumers, and the least burdensome regulatory approach among many options focuses attention of CPSC analyses on typical uses at typical levels under various regulatory options. The mandate for protection against "unreasonable risk" has an element of protecting individuals, but the mandated consideration of the costs and benefits of options means that the main concern is for how the number of users and the typical exposure during use will be affected by the various control options. That is, once the product has been determined to be toxic, the main focus is on population rather than on individual risk.

The statutes make no mention of protection of sensitive subpopulations from injury, although the CPSA [§9(e)] does mandate that the special needs of the handicapped and elderly be taken into account regarding the disruption to consumer convenience resulting from a potential rule.

**Environmental Protection Agency**

The Environmental Protection Agency (EPA) was created by executive order by President Nixon in 1970. The EPA was set up as an independent Federal agency to be the administrative home for a number Federal environmental programs that had previously been scattered over the Executive Branch. The programs out of which the EPA was cobbled had their own legislative authorities and histories. Because the consolidation was by executive order (and not through a new environmental act specifying a melding and recasting of these programs), the various components of the new EPA retained their different legislative mandates, regulatory powers, and scopes. Many of the laws were amended during the early years of the EPA, tailoring their treatment of issues of particular concern. In addition, new laws were added to bring additional environmental problems into the ambit of the Federal environmental effort.

The result is that, even twenty-five years later, the EPA represents a collection of

environmental programs that has only partly been consolidated and centralized. Risk analysis is used in support of regulation and rulemaking under a half-dozen major environmental laws and a number of minor ones. Although the role of risk assessment, particularly quantitative risk assessment, has grown largely since EPA's founding, the separation of regulatory programs has had an effect on risk assessment practices in various parts of the agency. The history of risk assessment at EPA has been marked by ongoing issues of consistency versus case-specificity of risk assessment methods and analyses, and consolidation versus dispersion of the conduct of risk assessment.

The dispersion of risk assessment activity over parts of the EPA makes the issue of coordination and maintenance of consistency particularly important to this agency. There are several means in place toward this end. They include the publication of a series of risk assessment guidelines, development of methodology documents, the chartering of several cross-agency groups to coordinate and harmonize practices and to resolve methodologic and policy questions that may arise, the reliance for advice and scientific guidance on external experts through the EPA Science Advisory Board, and the maintenance of a computerized, publicly available data base of agency-wide consensus on risk assessments.

The risk assessment methods employed by the Environmental Protection Agency have much in common with those used elsewhere, reflecting the general practices, standards, and precepts of the field. Risk assessment is a practical field, and the principles that have evolved reflect the concerns and ends of practitioners, including regulatory agencies and public health institutions, both national and international. The EPA has been an influential player in this development because of its major role in environmental regulation, the growing role of risk assessment in that regulation, and because the agency has made special efforts to define and develop the underpinnings of its methods through the promulgation of risk assessment guidelines and promotion of scientific discussions about risk assessment methods.

EPA's risk management practices are guided primarily by President Clinton's executive orders (Executive Order 12866 on Regulatory Planning and Review and Executive Order 12875 on Enhancing Intergovernmental Partnership). These revoke and replace executive orders from President Reagan, but include many provisions on similar matters. The EO 12866 directs agencies to conduct cost-benefit analysis for all "significant regulatory actions" and to promulgate regulations only when necessary due to "compelling public need." Regulatory approaches should be chosen to maximize net benefits, minimize the overall regulatory burden on society, and to be the most cost-effective means of achieving the desired end.

### Office of Pesticide Programs

The regulation of pesticides is carried out by EPA's Office of Pesticide Programs (OPP), which is a part of the Office of Prevention, Pesticides, and Toxics (OPPT). Pesticides are different than other potentially toxic compounds in that they are intended to be poisonous, at least to the pests they are designed to control, and they are intentionally introduced into the environment for that purpose. This situation naturally calls for the consideration of both costs and benefits,

and the statutes under which pesticides are regulated provide for such analysis.

Pesticide regulation falls into two parts, and each part is accomplished under a different statute. The *registration* of pesticides (i.e., licensing for sale and use in agriculture or extermination) is carried out under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). No chemical may be sold in the U.S. as a pesticide without such registration, which establishes the conditions of legal use. The question of *tolerances* for pesticide residues on foods as encountered by the consumer is regulated under the FFDCA.

FIFRA (7 U.S.C.A. §§136 to 136y) provides for the regulation of sale and distribution of pesticides, where pesticide is defined as "any substance or mixture...intended for preventing, destroying, repelling, or mitigating any pest, [or]...intended for use as a plant regulator, defoliant, or desiccant" [FIFRA §2(u)]. No pesticide may be introduced into commerce without obtaining a registration from the EPA. Registration is obtained through petition to the agency, with the petitioner providing information on the intended use, data on efficacy of the pesticide and its toxicological properties. The agency is empowered to ask for the provision of additional data, including the requirement for more toxicological testing, if the information is deemed necessary for the registration decision.

The Administrator may approve the petition if the pesticide "will perform its intended function" [§3(c)(5)(C)], and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment" [§3(c)(5)(D)], which are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of ...use" [§2(bb)]. Pesticides are registered either for general use or for "restricted use" [§3(d)], with the latter category specifying conditions of use such as application methods, amounts used, target pests, geographic restrictions and so on.

Once granted, registrations expire after 5 years, at which time the petitioner can apply for renewal of registration [§6(a)]. There are provisions for EPA to cancel a registration early [§6(b)] if the Administrator finds adverse effects could indeed be caused, but a decision to cancel must take into account "the impact...on the agricultural economy." Much of the modern registration framework was introduced into FIFRA by 1972 amendments (the Federal Environmental Pesticide Control Act, 7 U.S.C.A. §136), and a large number of previously registered pesticides had been "grandfathered in" under the lax pre-1972 procedures. Further amendments in 1988 required re-registration (or cancellation) of these within 9 years, a large burden on the agency's risk assessment apparatus.

In sum, the registration process under FIFRA amounts to the granting of a license for sale and distribution of a potentially dangerous chemical. The license is not unlimited; it specifies the conditions of use that are permitted, potentially including restrictions on the target pests, the amounts of pesticide used, the application method, frequency, and timing of use, training of applicators, the time that must elapse after application before workers can reenter a treated field, and the time that must elapse after application before the crop can be harvested.

Importantly, the registration also includes restrictions on which specific crops may be treated. Once registration is granted, however, all uses that fall within the specified restrictions become legal and permissible. That is, the regulatory power of registration is over permissible uses, not over actual practice within the permissible range.

To be granted a registration, the petitioner must demonstrate that the pesticide, when used on the proposed crops at the proposed levels, is effective at controlling pests and that, when used according to the restrictions, it will not cause unreasonable risk to humans or the environment. The definition of such adverse effects in FIFRA is very vague, but in practice it includes risk to the applicators and farmworkers, ecological risks, risks to homeowners from extermination procedures, and (through interaction with the tolerance setting process of the FFDCA, as discussed below) risks to consumers of treated foodstuffs. The mandate in FIFRA for balancing costs and benefits is similarly vague, comprising only the statement that "economic, social, and environmental costs and benefits" are part of the definition of what adverse effects are to be deemed "unreasonable." (The FFDCA is at least somewhat more specific on matters of both costs and benefits in regard to tolerances for residues on food.)

The FFDCA (21 U.S.C.A. §§321 to 394) provides for regulation of permissible contents of toxic substances in or on food, and pesticides are explicitly considered in its provisions. While primarily an FDA statute, the parts of the FFDCA applying to pesticides are administered by the EPA. The FFDCA is discussed in the section on FDA, but some key provisions are briefly reiterated here.

Tolerances are the concentrations (on a per weight basis) permitted to remain in or on food as it is available to the consumer. The process of setting tolerances is also by petition, with the petitioner submitting proposed tolerance levels along with toxicological information to demonstrate that such tolerances will be sufficiently protective. Tolerances of pesticides on raw, unprocessed agricultural commodities are regulated under FFDCA §408, which mandates that tolerances should be set "for pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience..., as safe for use, to the extent necessary to protect the public health." However, "appropriate consideration" must be given "to the necessity for the production of an adequate, wholesome, and economical food supply."

The processes of petitioning for registration and petitioning for tolerances are interconnected, and in practice they often occur concurrently. Although regulated under separate laws and following different procedures, the two processes have a practical linkage in that the conditions and limitations for use of the pesticide established during registration must clearly lead to residues experienced by the consumer that will be below tolerances that can be approved on health grounds. The approval of tolerances is based on exposure from the total diet, so each new approved use of a pesticide in the registration process leads to potential residues that "use up" part of the total allowable intake. Because each use of a pesticide must employ enough of the agent to be effective against pests, a registrant must carefully choose the particular crop and use restrictions for which registration is being sought to ensure that the sum of resulting residues will be below the level for which a tolerance can be approved on

consumer health grounds.

Because registration is regulation of a prospective activity, much of the analysis of exposures, use levels, benefits, and costs must be based on professional judgment. In many cases, the rigorous analysis of costs and benefits, and the economic and agricultural effects of using various alternative pesticides and pest control practices, arises when a registration renewal is in question or when a cancellation of registration is being considered.

OPP considers three categories of exposure: to consumers, to those occupationally exposed (which in practice focuses on applicators, but also includes farmworkers generally), and the general public exposed via non-dietary means (i.e., through environmental contamination). As with most regulatory programs, there is no written rule or policy regarding the level of risk that must be deemed acceptable, but (also as with most agencies) there is understood unwritten practice that is revealed in the examination of regulatory decisions taken by the agency.

OPP generally tries to ensure that individual risks in all three categories do not exceed $10^{-6}$ for lifetime exposure. Until recently, the goal for occupational exposures was somewhat higher, closer to $10^{-4}$, but this was lowered to match the other categories during the tenure of Assistant Administrator Linda Fisher, and has remained so since. In the case of consumers, the $10^{-6}$ risk applies to cumulative exposure to the pesticide from all dietary sources, with these estimates usually being based on conservative residue estimates but population average rates of consumption of food types. As noted earlier, it is difficult to determine when this combination is conservative, especially vis-à-vis the high end of levels of consumption of particular foods. For pesticide applicators, the exposure assumptions are not particularly conservative in terms of exposure per treatment, but there may be assumptions about maximum allowable use of the agent that are not met in reality.

These risk criteria are nominally for individual risk levels. However, the fact that consumer risks are calculated based on consumption levels averaged over the entire population makes these risk calculations apply to the whole population (at least on average, and bearing in mind the conservative residue assumptions). Thus, the criterion really hinges on a kind of population risk measure. High individual cancer risks that result because of high consumption of the affected food products is not captured because of the nature of the exposure analysis.

For non-cancer risks, many of the same considerations apply; high end individual exposures are not captured by the exposure assessment. However, differences in average exposure in each of 22 demographic subgroups are considered.

The consideration of costs and benefits is vaguely specified in the pesticides statutes, but registrations and tolerances are set bearing in mind the balancing of the risks engendered with the costs to agriculture and food prices. As registrants tailor their petitions for which crop treatments are to be approved, limitations on uses, and tolerances, they consider the economic and agricultural benefits to be gained by different combinations of uses that might be

approvable. Those specific uses that are most efficacious and economically favorable to agriculture are more likely to be proposed by the registrant because they will lead to a better market for the pesticide once registered.

### Office of Pollution Prevention and Toxics

The EPA's Office of Pollution Prevention and Toxics (OPPT) is a relative newcomer among EPA regulatory programs, having been founded (under the original name of the Office of Toxic Substances) to implement the 1976 Toxic Substances Control Act (TSCA). In addition to its original role as implementer of TSCA, OPPT has been given responsibility for pollution prevention programs, regulation of certain abatement programs (such as that for asbestos), and the administration of the Toxics Release Inventory, mandated under amendments to the Superfund law. The focus of risk assessment in OPPT, however, is under TSCA.

TSCA (15 U.S.C.A. §§2601 to 2692) was conceived of as a "gap-filling" statute; Congress recognized that the existing array of environmental legislation covered risk posed by chemicals only under those particular exposure conditions each program was mandated to regulate. Moreover, this regulation was often in reaction to existing pollution, and its efficacy was hampered by lack of information on the chemicals in question. TSCA was passed in 1976 as an attempt to take a comprehensive approach to regulation of toxic substances, stressing properties of the chemical rather than of particular exposures to the chemical, and encouraging the development of information regarding toxic properties and exposures. The aim was to prevent risks from toxic substances that might "fall through the cracks" between other environmental statutes. This cross-cutting role has meant that throughout its history, there have been ongoing questions about TSCA's overlap with other environmental statutes.

The provisions of TSCA implement a set of policy statements set out at the beginning of the act [TSCA §2(b)]. First, "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment." Moreover "the development of such data should be the responsibility of those who manufacture and...process such chemical[s]." Second, the government should have adequate authority "to regulate chemical substances...which present an unreasonable risk of injury to health or the environment," including imminent hazards. Finally, exercise of this authority should "not...impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose...to assure that...such chemical substances...do not present an unreasonable risk." Section 2(c) goes on to require that "the Administrator [of EPA] shall consider the environmental, economic, and social impact of any action" taken under the act.

Section 4 of TSCA relates to testing and gathering of information on chemicals. It authorizes rulemaking requiring manufacturers to conduct toxicological testing for "carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effects with may present an unreasonable risk of injury to health or the environment" [§4(b)(2)(A)]. The burden is on EPA to show that such testing is necessary, however. (This is unlike testing mandates under FIFRA or FFDCA, in which the agency can

without rulemaking call for all information needed to grant or deny petitions.) The substance must present possibilities of unreasonable risk, "enter the environment in substantial quantities," or be likely to have "substantial human exposure" [§4(a)], all criteria that require the agency to do some preliminary risk assessment. An Interagency Testing Committee is established to set testing priorities. (Through this means, §4 is a vehicle for various Federal regulatory groups to obtain testing mandates, as long as their interests parallel those of EPA.) In practice, testing is done through enforceable negotiated consent agreements ever since a lawsuit challenged the earlier practice of negotiated voluntary testing [NRDC v. EPA, 595 F.Supp. 1255 S.D.N.Y.1984)].

TSCA makes a distinction between new and existing chemicals. The latter are those on a “list of each chemical substance which is manufactured or processed in the United States”, which EPA is required to compile and maintain. Anyone proposing a new chemical (i.e., one not yet on the list), or to undertake a “significant new use” of an existing chemical, must give notice to EPA, along with test data and information bearing on its potential risk. EPA reviews the submission and permits the chemical’s manufacture, suspends its manufacture or distribution, restricts its use pending the provision of further data, or initiates rulemaking to regulate its manufacture or distribution. Once a chemical enters commerce, it becomes an “existing” chemical.

In essence, the Toxic Substances Control Act aims at establishing a system of both public and private vigilance against health and environmental risks from chemicals in commerce that might not be noted or covered by other regulatory authorities. The mandate is to avoid "unreasonable risk of injury to health or the environment," while balancing the benefits of any controls against "unnecessary economic barriers" [§2(b)]. The onus is on EPA to show that unreasonable risk exists, but if it does so, controls are to "protect adequately" against the risk [§6(a)]. In promulgating any such rule, the Administrator must "consider and publish a statement with respect to...the effects...on health and the magnitude of the exposure of human beings,...the effect on the environment,...the benefits of such substance...for various uses and the availability of substitutes..., and...the reasonably ascertainable economic consequences of the rule, after consideration of the effects on the national economy, small business, technological innovation, the environment, and public health" [§6(c)(1)].

In other words, EPA is given rather general authority to seek out and regulate any "unreasonable risk" wherever it may be found, but what might otherwise be sweeping authority is reigned in by the requirement to consider economic and social impact. The act also offers a myriad small checks on this authority in addition to one major one—"If...a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law" [§6(c); §9(a)(1)], that other law must be deferred to unless it can be shown to be in the public interest to regulate under TSCA. In practice, this "hand-off" to another regulatory authority almost always happens, and most assessments of risk due to major "existing" chemicals (as opposed to "new" chemicals, as discussed above) are referred to the CPSC, OSHA, or another part of EPA.

In the analysis of new chemicals, OPPT generally seeks margins of exposure relative to NOAELs of 100. Cancer risks are generally ruled acceptable if they fall below $10^{-4}$ lifetime individual risks for occupational settings and below $10^{-5}$ for general population exposures. It should be borne in mind that these are rough criteria, given the screening nature of new chemical assessments.

TSCA is a cost-benefit balancing statute, but a rigorous analysis of costs and benefits is usually only possible for actions contemplated under §6. The much more frequent new chemical analyses and development of risk justifications for test rules employ a more qualitative consideration of costs and benefits.

### Office of Air and Radiation

Until about the 1950's, air pollution regulation was framed in terms of control of public nuisances; local and state laws aimed to control particular emissions sources that created visible and direct public annoyance. Growing awareness of the chronic health effects of air pollution, and a growing concept of unsullied air as a public resource held in common and in need of public protection, led to various control measures, including the passage of the Clean Air Act (42 U.S.C.A. §§7401to7671q) in 1963. Initially, the Federal role was largely limited to research, with primary responsibility for control left to the states. It became evident, however, that state control alone was insufficient to deal with cross-boundary movement of polluted air. Moreover, states varied widely in the vigor of their enforcement, prompting fears that states would vie to attract industry by providing lax regulatory environments. The inherent conflict is that the sources of air pollution are local, and hence properly in the realm of state and local regulatory control, but the effects are on the common resource, so that irresponsibility of the few despoils the air for all—a classic "commons" problem.

This initial, desultory phase of air pollution control ended in 1970 with the passage of amendments to the Clean Air Act that for the first time created a strong Federal role. Implementation of pollution control plans, issuance of emissions permits, and enforcement were still the province of the states (as they continue to be today), but these state activities had to accomplish the meeting of Federally mandated and uniform standards for air quality, with provisions to ensure that the states would rigorously enforce the standards.

The Federal standards are of two basic kinds: standards for air quality and standards for the performance of pollutant sources in terms of allowable emissions. Standards for air quality specify uniform national definitions of what constitutes acceptably clean air, and regulatory programs (much of which occur at the state level with EPA oversight) covering the spectrum of sources of the pollutant by a variety of means are then aimed at achieving air quality at least up to those standards. Performance standards for sources are aimed at establishing uniform national limits on the emissions from particular kinds of sources, including motor vehicles (mobile sources) and stationary sources. (For some purposes, the CAA distinguishes among "major" and "minor" sources based on amounts of emissions, and on "point" and "area" sources based on whether the emissions come from a specific, identifiable facility or from

more general human activity not easily localized to a few geographic coordinates.)

Sections 108 and 109 of the CAA call for the development of air quality criteria for the widespread "criteria pollutants." Criteria pollutants include sulfur dioxide, particulates, ozone, nitrogen dioxide, carbon monoxide, and lead. (The criteria pollutants are not named in the statute, but are those with "emissions which...may reasonably be anticipated to endanger the public health or welfare...[and] result...from numerous or diverse mobile or stationary sources" [§108(a)(1)]. Over time, lead has been added to the list and hydrocarbons dropped.) The criteria "shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health and welfare" [§108(2)]. So-called "primary" ambient air quality standards are to be standards which, "allowing for an adequate margin of safety, are requisite to protect the public health" [§109(b)(1)]. (There are also "secondary" standards that consider non-health effects.) Legislative history has led the "ample margin of safety" mandate to be interpreted as requiring protection of most of the population, including sensitive population groups (e.g., asthmatics, the elderly) but not the most exposed individual or the most sensitive member of a sensitive group. These are to be purely health-based criteria, and are not dependent on costs or technical feasibility.

It is up to the states to provide plans for controlling pollution so as to attain these National Ambient Air Quality Standards (or NAAQSs); section 110 calls on each state to submit to the EPA for approval "a plan which provides for implementation, maintenance, and enforcement of such primary standard in each air quality control region (or portion thereof) within such State" [§110(a)(1)]. Such State Implementation Plans (SIPs) are to include "enforceable emission limitations and other control measures...(including economic incentives such as fees, marketable permits, and auctions of emissions rights)...as may be necessary" [§110(a)(2)(A)] and must provide for monitoring and enforcement. Section 111 provides for Federal standards of performance for new sources of criteria pollutants "which may reasonably be anticipated to endanger the public health or welfare." Sections 160-169B provide for the prevention of significant deterioration of air quality in regions that are already in attainment of the NAAQSs.

Mobile source emissions are addressed in §202; emissions standards for new motor vehicles may be set for "any air pollutant...which may reasonably be anticipated to endanger public health or welfare" [§202(a)(1)]. Although the main concern has been motor vehicles as a source of criteria pollutants, mobile source toxics are also addressed in §202(l), which calls for study of "emissions that pose the greatest risk to human health or about which significant uncertainties remain" and calls for standards for these, including explicit requirements for regulation of benzene and formaldehyde. Fuel formulation may be regulated under §211, and manufacturers of additives may be required to conduct "tests to determine potential public health effects...including...carcinogenic, teratogenic, and mutagenic effects." Such regulations must consider technical and economic feasibility.

Air toxics are regulated under CAA §112. The amendments of 1990 added a list of 189 compounds designated as hazardous air pollutants [§112(b)]. Chemicals may be added to this

list by rule if found to "present...a threat of adverse human health effects." Compounds may be deleted from the list by petition if "adequate data" determine that "emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effects to human health or adverse environmental effects" [§112(b)(3)(C)]. The EPA must build and maintain a list of the principal areas sources and of "major sources" of these pollutants (i.e., those emitting more than 10 tons/year of any one listed chemical or 25 tons/year of any combination). §112 mandates that emissions of compounds on its specified list be controlled to the extent feasible on technical and economic grounds, regardless of the risk they may pose (excepting the *de minimis* delisting). Section 112(f) calls for the examination of risks that may remain after such technical controls are in effect; EPA must develop methodology to estimate such "residual risk" and recommend legislation to address any such risk that may be found. If Congress does not act on this recommendation, the EPA must promulgate emissions standards "with an ample margin of safety to protect the public health." That is, if residual risks exist after Maximum Available Control Technology (MACT) standards are in effect, there is a fallback to the pre-1990 basis for air toxics regulation. In particular, the promulgation of such standards is triggered if MACT controls "do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source...to less than one in one million" [§112(f)(2)(A)]. The standards adopted need not protect this maximally exposed individual (MEI) to the $10^{-6}$ level—the criterion is instead the "acceptable risk" policy developed after the vinyl chloride decision [54 FR 38044]—but the existence of a $10^{-6}$ risk triggers the consideration of residual risk regulation.

Thus, despite the fact that the 1990 amendment of §112 was designed to reduce the role of risk assessment in air toxics regulation (and the consequent questions and delays as uncertainties in those assessments are debated), there are several places where risk assessment is called for in evaluating the technology-based controls. These include (1) the listing and delisting of hazardous air pollutants, which depends on whether a chemical may "present...a threat of adverse human health effects;" (2) the *de minimis* delisting of source categories, which requires less than a $10^{-6}$ risk to the MEI; (3) the triggering of post-MACT standards to address residual risk, which also requires less than a $10^{-6}$ risk to the MEI; and (4) the offset trading of one pollutant for another based on whether the increased emission is "more hazardous." Of these, the third (the residual risk determinations) is the one based primarily on EPA initiative, but it is one that will require extensive analysis, because each source of each hazardous air pollutant should in principle be evaluated at a level of detail such that the individual near each source at highest risk can be characterized.

For criteria pollutants, standards are set by using a complex characterization of the distribution of exposure levels in the population that would be expected under a specified air quality criterion. When combined with the exposure-response relationships, this gives a projection of the number of health effects incidents to be expected in the exposed population. Both the exposure and dose-response components are estimated based on extensive data; they require little extrapolation and few default assumptions, and the estimates of health impact are thus characterized as unbiased estimates without added conservatism. Point estimates rather than

"upper bounds" are used. Ranges of risk are estimated corresponding to the experience of sensitive groups.

The risk mandate for protection of public health with an adequate margin of safety is accomplished by setting air quality criteria such that most of the population is protected, including sensitive sub-groups and highly exposed individuals, but not necessarily the most sensitive or most exposed person. There is no fixed level of acceptable risk, which depends on the nature of the health effect in question, the size of the group potentially affected, and the degree of uncertainty about effects and exposure. These decisions are prohibited from considering costs and feasibility.

Although the effects in question are non-cancer health effects, they are generally held not to display a practical threshold exposure for effects. The methods recognize that even quite protective standards do not banish the possibility of some few people being affected. In this way, the situation is similar to that of carcinogens, where "safety" cannot be absolute, and so a reasonable degree of protection must be defined. For criteria pollutants, the risk characterization focuses on population risk, that is, on the health impact on the population as a whole, recognizing that that impact is most likely to appear among the most sensitive and most exposed. There is no real individual risk criterion.

In the analysis leading up to the development of a proposed ambient air quality standard, an analysis may be done of the effects that would be expected if the whole population were exposed to air just at the limit of the standard. Although this is not the primary decision criterion, such an analysis provides an idea of potential impact if all the air were indeed as polluted as is being allowed. This situation is unlikely to occur in practice in a compliant area, since the air quality criteria represent the allowable maximum in what is always in reality a variable level of air quality. (It is interesting to compare the minor role this analysis plays for criteria pollutants to the major role that a similar analysis plays in the regulation of pesticide residues, as discussed in the section on the pesticides office. In that case, the regulatory decision is made on an analysis presuming that all foods contain their maximally allowed residues, even though a distribution with mostly lesser values is likely to be true. The chief difference, of course, is that pesticide residues are more readily manipulated up to their allowable level than is ambient air quality.)

In the case of air toxics, the application of analysis as now being formulated to regulatory decisions is still in the future, and so it is difficult to characterize with confidence. The presumption is that for most sources of most hazardous air pollutants, the maximally available control technology will be sufficient and further regulation not needed. Actual regulations of residual risk, where necessary, will be made under the criteria prevailing before the 1990 amendments, that is, the criteria mandated by the D.C. District Court's 1987 "vinyl chloride decision" [NRDC v. EPA, 824 F 2d 1146]. These criteria have an individual risk component, that an individual exposed to the maximum fenceline concentration for 70 years should not have a risk exceeding $10^{-4}$. They also have a population risk component, that as few people as possible should have a risk greater than $10^{-6}$. The $10^{-4}$ level is the policy definition of "safe,"

fulfilling the mandate for a regulation that "protects the public health." It is intended that this level of safety be guaranteed even to someone who chooses to fulfill the fenceline exposure scenario, whether or not someone actually does so. The aim to protect as many people as possible from the $10^{-6}$ risk level is interpreted as the provision of an "ample margin of safety" as provided for in the CAA. In the case of non-cancer effects, it is presumed that exposures below the reference concentration (RfC) fulfill both the mandate for safety and for an ample margin of safety. Given the amount and site-specific detail of exposure analysis required to trigger post-MACT regulation, it is likely that the exposure assessments for such regulations will be much less conservative and "worst-case" than may have been the case prior to 1990. Although the regulatory criteria are nominally the same, the risk outcome and the stringency of regulation may end up being somewhat different.

### Office of Water

Regulation of water pollutants is carried out by EPA's Office of Water (OW). The Office of Water administers two major statutes, the Federal Water Pollution Control Act (better known as the Clean Water Act or CWA 33 U.S.C.A. §§1251 to1387) and Title XIV of the Public Health Service Act (better known as the Safe Drinking Water Act, or SDWA 42 U.S.C.A. §§300f to 300j-26). The Clean Water Act has as its goal to maintain and improve the cleanliness and biological integrity of the nation's waters, including lakes, rivers, and navigable waters. The aim is to make these waters "fishable and swimable." In many ways, the nature of the pollution problem and the nature of the statutory approach parallel that of the Clean Air Act, discussed in an earlier section; the nation's waters constitute a broadly distributed common resource the quality of which is impinged upon by the activities of many local sources of contamination. Each source of effluent is not solely responsible for the resulting water quality, but the collective burden of discharges may result in unacceptable deterioration of the resource as a whole. The regulatory approach is the promulgation of nationwide uniform criteria defining the degree of water quality that is compatible with intended uses and states of different water bodies. (The criteria are health-based, but they are not rules, and are themselves unenforceable.) These water quality criteria are coupled with enforceable technology-based standards for allowable discharges from point sources, which (also like the Clean Air Act) are implemented through permitting regulations by the states. It is the responsibility each state to conduct regulation of discharges such that the applicable water quality criteria are met for the state's waters.

The Clean Water Act opens with a "Congressional declaration of goals and policy" [CWA§101] that sets ambitious goals for the nation, declaring "it is the national goal that the discharge of pollutants into navigable waters be eliminated by 1985" and that "the discharge of toxic pollutants in toxic amounts be prohibited." The history of amendment of the CWA has been in part the history of rescheduling and delaying the milestones and timelines for achievement of the mandated complete solution to the nation's water pollution problems, as issues of feasibility and practical impediments are encountered. Nonetheless, the act has provisions for citizen lawsuits that has led to the agenda of water regulation being driven largely by court orders and consent agreements.

The CWA distinguishes "conventional" pollutants from "toxic" pollutants. The former are largely those associated with discharge of sewage and nutrients, such as fecal coliform bacteria, suspended solids, and sources of biological oxygen demand. In some ways, they are analogous to the criteria air pollutants, the inevitable, widespread products of human activity that are dangerous by virtue of their overproduction if uncontrolled. The present report will concentrate on the "toxic" water pollutants, analogous to the air toxics, that are treated and analyzed as exposures to toxic chemicals.

As enacted in 1972, the CWA required implementation of standards for toxic pollutants providing an "ample margin of safety;" that is, feasibility considerations were not allowed. For reasons similar to the difficulties seen in regulating air toxics under a similar standard, the CWA was amended in 1977 to include a named list of chemicals [§307(a)(1)] to be regulated within three year with regulation to be based on "best available technology" (abbreviated BAT, a feasible technology approach similar to the 1990 revision of the Clean Air Act). A residual risk-like provision permits the Administrator to set a more stringent "ample margin of safety" standard if necessary [§307(a)(4)].

Section 304 of the CWA calls on EPA to establish "criteria for water quality accurately reflecting the latest scientific knowledge...on the kind and extent of all identifiable effects on health and welfare," including ecological effects. That is, the criteria are to be entirely health- and effect-based. For carcinogens, no level can be named that fulfills the designation of "safe," so the criteria are presented as water concentrations that would be expected to lead to lifetime cancer risk levels of $10^{-5}$, $10^{-6}$, and $10^{-7}$ when consumed at the standard rate for a lifetime. For non-carcinogens, water quality criteria are developed that will not violate the RfD. (Cancer risks and RfDs are calculated by the standard methods.) These calculations are based on individual risk, but the criteria are to apply nationwide, so it is presumed that any criterion will apply to a significant number of people. Actual exposures for many people will of course be less, but exposures will be higher for a significant number, both because of the midrange nature of the consumption assumptions and because much surface water in the country is not in compliance with the water quality criteria which (despite the policy statements set out at the beginning of the CWA) remain goals to be striven for in many cases.

The second major statute administered by the water office is the Safe Drinking Water Act, which regulates the contamination of drinking water provided by public water systems. The act took its current form after 1986 amendments that followed a report from the Office of Technology Assessment documenting widespread serious incidents of contaminated drinking water (Findley and Farber, 1992). As with the Clean Water Act, there are a number of statutory timelines for promulgation of regulations that set a very ambitious schedule, one that has been difficult to meet in practice. Regulation is based on the permissible levels of contamination of finished water, that is, as it appears to consumers at the end of the tap. These standards, called national primary drinking water regulations, are promulgated by EPA [§1412(b)(3)] and enforced by the states, which can opt to set more stringent standards [§1413]. The standards apply to all public water supplies serving at least 25 people. Section

1412(b)(3)(A) calls on the EPA Administrator to "promulgate national primary drinking water regulations for each contaminant...which...may have any adverse effect on health of persons and which is known or anticipated to occur in public water systems." The standards are set on a health basis alone, but the requirement is to come as close to meeting them as is technologically feasible. Primary enforcement authority is with the states, which can opt for more stringent standards.

A standard specifies two levels of contamination of drinking water by the compound in question: a "maximum contaminant level goal" is set "at a level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." For each standard with such a goal there is also specified "a maximum contaminant level which is as close to the maximum contaminant level goal as is feasible" [§1412(b)(4)], where "feasible" means "feasible with the use of the best technology, treatment techniques and other means which...are available (taking cost into consideration)." (In practice, achievability is judged by affordability of control technology to larger public water suppliers; smaller suppliers may have economic difficulty complying. If contaminant levels cannot be measured, a standard can specify a treatment technique to be used.)

In other words, maximum contaminant level *goals* (known as MCLGs) are to be set solely on health grounds to protect with an adequate margin of safety. Maximum contaminant *levels* (known as MCLs) are levels that are practically achievable. It is the technically feasible MCL, and not the health-protective MCLG, that is the enforceable standard. The level set for the MCL depends on available technology, and the appropriate level can change with technological advance. Section 1412(b)(9) provides for periodic revision of MCLs to address this.

The main reason for the MCLG/MCL distinction is that carcinogens, being presumed to be without a threshold, have no safe level. (Clearly, it is also possible that an agent with a threshold has that threshold level lower than is technically achievable.) That is, the common problem faced under all statutes requiring "safety" (especially with an "adequate margin") when dealing with non-threshold toxicants is addressed under the SDWA by controlling contamination to as low a level as technically and reasonably possible without particular regard for how much risk is estimated to remain. This is similar to the "carcinogen policy" at OSHA as it existed before the Supreme Court benzene decision and practice at the EPA Office of Air and Radiation before the vinyl chloride decision, both of which policies were overturned by those decisions, as discussed in the sections on those groups. The chief difference is that the SDWA explicitly decouples the risk and the feasibility issues.

It is important to remember that MCLs are set on a technical feasibility criterion, with the feasibility issue being affordability of controls by public water providers. In some cases, other regulatory programs (notably Superfund and Solid Waste) use the water office's MCLs as though they were health-based criteria, for example as standards to be attained for cleanup of or release into water. The entirely reasonable rationale is that requiring concentrations to be lower than allowable in tap water seems to be unwarranted, but the inappropriate implication is

sometimes made that attainment of the MCL is a standard of health protection.

### Office of Solid Waste

The regulation of hazardous solid waste is the responsibility of EPA's Office of Solid Waste (OSW). The office implements the 1976 Resource Conservation and Recovery Act (RCRA 42 U.S.C.A. §§6901 to 6992k), which amended the Solid Waste Disposal Act. The purpose of the act is to develop mechanisms for ensuring stewardship over hazardous compounds from their generation to their proper disposal. The act's provisions set up an extensive set of requirements for reporting and record keeping in addition to standards for generators and transporters as well as treatment and disposal practices. That is, the aim is to ensure that hazardous wastes are kept track of—and that ownership and responsibility for those wastes are not lost or obscured—during storage, transportation, and disposal. The provisions can be seen as a means to avoid the processes leading to dangerous hazardous waste sites, especially those at which responsibilities for the wastes are no longer assignable.

RCRA declares it to be "the national policy of the United States that, wherever feasible, the generation of hazardous waste is to be reduced or eliminated as expeditiously as possible. Waste that is nevertheless generated should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment" [RCRA§1003(b)]. Hazardous waste is defined as solid waste that may "cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness" or otherwise present a potential hazard to human health or the environment [§1004(5)].

Section 1003 requires EPA to identify hazardous wastes and to list those wastes that should be subject to RCRA's provisions. (There is a provision for delisting a waste as well [§3001(f)].) Listing is to take into account "toxicity, persistence, and degradability in nature, potential for accumulation in tissue" as well as factors such as corrosiveness and flammability. EPA is empowered to issue standards "as may be required to protect human health and the environment" in three broad areas: generation, transport, and disposal. Generation is covered by §3002, requiring standards for record-keeping, handling, labeling, and use of appropriate containers. Section 3002 sets up a manifest system to ensure that the waste is kept track of and responsibility for it assigned, from its generation to eventual disposal, even if this involves transactions and transfers of ownership of the waste. Transport standards are mandated in §3003, which also incorporates the manifest system, as does §3004, which governs storage and disposal. Disposal standards are largely framed in terms of technology that must be used. Land disposal is prohibited unless "to a reasonable degree of certainty,...there will be no migration of hazardous consituents from the disposal unit...for as long as the wastes remain hazardous." RCRA also provides for EPA regulation of cleanup of currently active industrial sites that hold RCRA permits and requires permits for waste incineration and other disposal methods in addition to land storage.

Given the largely technical and procedural nature of its provisions, RCRA has relatively little

to say about risks and risk assessment. It simply calls for EPA to act to ensure that hazardous waste management practices "are conducted in a manner which protects human health and the environment" [§1003(a)(4)]. Section 3019(b) states that when, in the Administrator's judgment, "a landfill or a surface impoundment poses a substantial potential risk to human health, due to the existence of releases of hazardous constituents, the magnitude of contamination,...or the magnitude of the population exposed", a request may be made for the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a health assessment of the site. Such a health assessment is not a risk assessment *per se*, but it contains many of the elements of one, including characterization of the exposures and potential exposures around the site, identification of potential exposure pathways, review of the known health effects of the hazardous constituents present, surveys of health complaints in the population in the vicinity of the site, and the review of applicable health-based exposure standards that may exist.

In practice, the evaluation of toxicity information and the potencies of substances is largely drawn from other EPA sources outside of OSW, including information on the IRIS database, reports produced by the EPA Office of Research and Development, maximum contaminant levels taken from the EPA Office of Water, and methods borrowed from the Office of Emergency and Remedial Response (Superfund). In fact, the analysis of hazards posed by inadequate waste disposal sites has much in common with the analysis conducted by Superfund for abandoned sites. OSW combines this information with its own exposure analyses and conducts risk characterization appropriate to its uses of risk analysis.

Risk calculations represent individual risks under exposures that are calculated with conservatism tempered where possible by the use of distributional and Monte Carlo analysis. Individual lifetime cancer risk levels of $10^{-5}$ or so from unregulated disposal trigger listing of a waste as a hazardous substance and hence subject to RCRA controls on handling and disposal. Newer methods are adopting a range of $10^{-4}$ to $10^{-6}$ as a range in which this decision can be made. Delisting a substance as a hazardous waste requires a risk estimate less than $10^{-6}$ for unregulated disposal. Incinerator permits have usually been granted if risks are below $10^{-5}$. Remediation of active waste sites depends on many non-risk technical and other factors, but a post-remediation risk level of $10^{-4}$ to $10^{-6}$ is aimed at.

RCRA also has little to say about costs, neither requiring nor prohibiting their consideration (Schierow, 1994).

### Office of Emergency and Remedial Response

The Superfund program was created by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, 42 U.S.C.A. §§9601 to 9675) of 1980 and its subsequent amendments, the 1986 Superfund Amendments and Reauthorization Act (SARA), to address the need for cleanup of the nation's hazardous waste sites. The program is administered by the EPA Office of Emergency and Remedial Response (OERR). With no state unaffected by past hazardous waste disposal practices, the Superfund program has

perhaps done more than other programs to make the use of risk assessment a local issue. At the same time, it has become a lightning rod for criticism of the U.S. EPA's use of risk assessment for regulatory decision-making in general.

Neither CERCLA nor SARA specifically mention risk assessment, when it is to be used, what procedures to follow, or what levels of risk warrant remedial action or (in the case of specific action) define what actions are to be deemed "protective." The statutes provide a broad mandate to pursue action on contaminated sites that "may present an imminent and substantial danger to the public health or welfare" [§102]. Risk assessment is used under Superfund to define hazardous substances and the amounts of release that must be reported to EPA ("reportable quantities"), rank the risks posed by hazardous waste sites and identify the action priorities among them, including the addition of sites to a National Priorities List (NPL) of high-priority sites, and evaluating the effectiveness of options for remediation (which are chosen on various non-risk grounds in addition to considering risk reduction effectiveness).

Specific policies on risk assessment have been laid out in the National Contingency Plan (NCP, the body of regulations implementing CERCLA and its amendments) and in numerous guidance and policy directives issues pursuant to the NCP. The NCP, like the statutes themselves, does not specifically define the use and form that risk assessment takes in the Superfund site assessment and remedy selection process. However, especially in the area of remedy selection, the NCP interpretation of SARA sets the criteria which must be met and balanced in remedy selection and can profoundly affect the role that risk assessment plays in cleanup of hazardous waste sites. It is important to recognize that although regulatory policy has given risk assessment a role in the evaluation and remediation of hazardous waste sites, it is one of many considerations in the selection of a final remedial alternatives. The NCP establishes nine criteria by which remedial alternatives must be evaluated:

- Overall protection of human health and the environment;
- Compliance with existing regulations and local requirements;
- Long-term effectiveness and permanence;
- Reduction of toxicity, mobility, or volume through treatment;
- Short-term effectiveness;
- Cost;
- Implementability;
- State acceptance; and
- Community acceptance.

The first two criteria are considered threshold criteria that must be met before a remedy can be evaluated fully by the other criteria. The "overall protection" includes consideration of risks that may be generated as a result of the remedial action (e.g., risks to remediation workers or to the public surrounding a site). However, the strong preference for permanent remedies voiced in SARA and codified in the NCP creates a more technology-based approach to remedy selection, which critics argue can override the implications of a risk assessment.

Nominal decisions about cleanup are influenced (to the degree they are based on risk at all) on individual risk levels. These risks are based on standard scenarios of exposure depending on the anticipated future land use, and on estimates (often upper end estimates) of the concentration of contaminants currently at the site. Exposures are often figured as RMEs, or reasonable maximum exposures. RMEs correspond to exposure scenarios in which some contributing variables are set at conservative, upper-bound values, but most are set at population average values.

Policies regarding the level of risk that constitutes a hazard have evolved in the Superfund Program. At the outset of the program, a $10^{-6}$ lifetime cancer risk was frequently the benchmark against which estimated risks for a site were judged. Under the current NCP and subsequent policy directives, estimated risks at a site are evaluated against a risk range of $10^{-4}$ to $10^{-6}$. The NCP states: "For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between $10^{-4}$ to $10^{-6}$ using information on the relationship between dose and response." The NCP does not address the definition of “protective” in the context of exposure to non-carcinogens. In practice, however, exposures to contaminants resulting in hazard quotients or hazard indices exceeding 1 are considered to carry an increased potential for adverse noncancer health impacts.

An important and unique feature of Superfund risk assessments is the consideration of exposure to many chemicals simultaneously. This practice is attributable to the need of risk assessment to evaluate waste sites as health hazards, and not particular chemicals. Superfund does not consider the possible exposure of some people to multiple hazardous waste sites, however.